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Schubert et al.

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(45) **Date of Patent: Sep. 22, 2015**

(54) **SHIELDABLE NEEDLE ASSEMBLY WITH BIASED SAFETY SHIELD**

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(73) Assignee: **Novo Nordisk A/S**, Bagsvaerd (DK)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 418 days.

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(51) **Int. Cl.**
A61M 5/32 (2006.01)
A61M 5/34 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 5/326*** (2013.01); *A61M 5/3202* (2013.01); *A61M 5/347* (2013.01); *A61M 2005/3247* (2013.01); *A61M 2005/3267* (2013.01)

(58) **Field of Classification Search**
CPC A61M 5/326; A61M 2005/3267; A61M 2005/3247; A61M 5/3271; A61M 5/3257; A61M 5/3202; A61M 2005/325; A61M 5/321; A61M 5/50
USPC 604/110, 251, 187, 93.01, 192, 197, 604/198
See application file for complete search history.

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Assistant Examiner — William Carpenter
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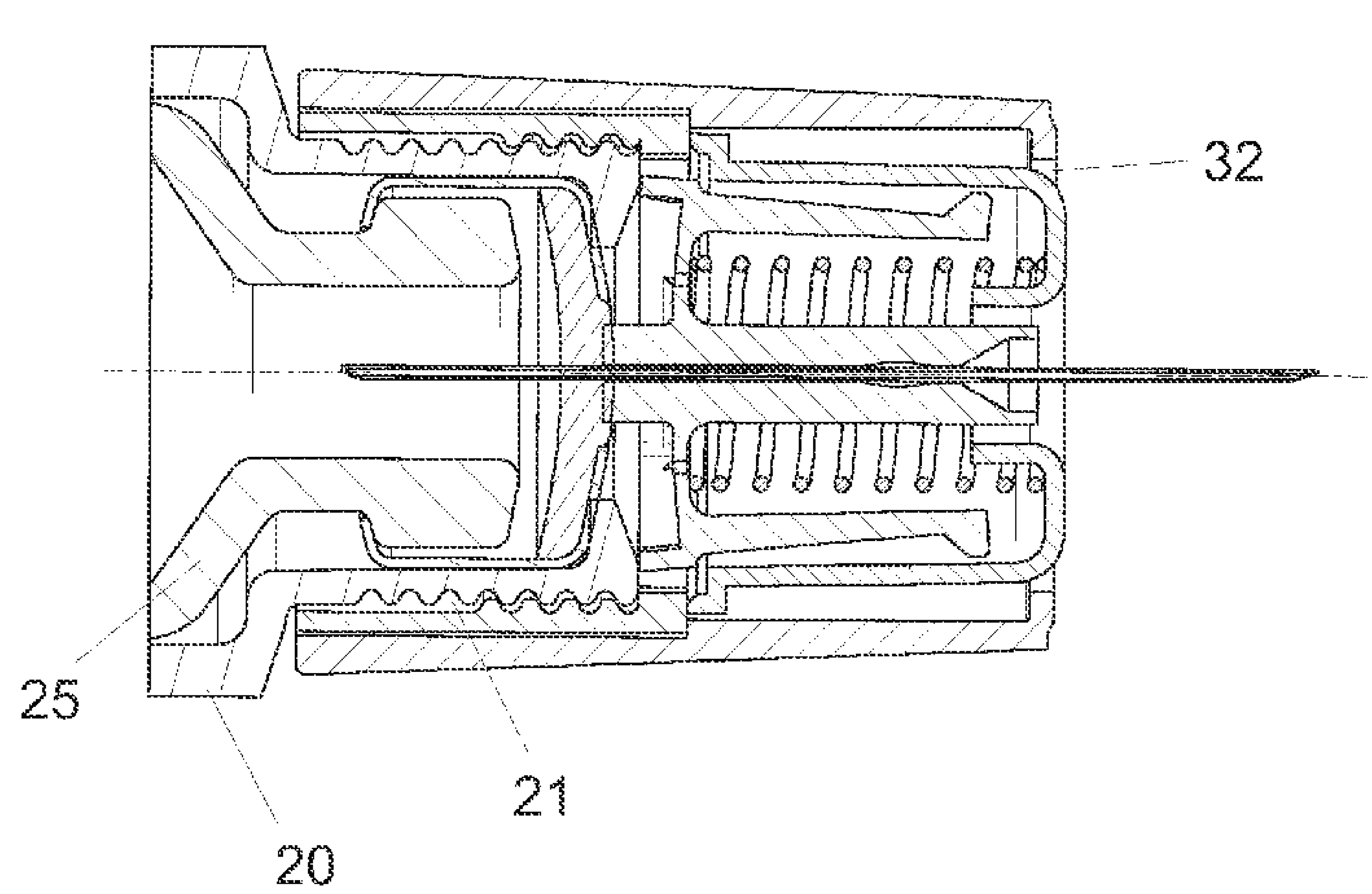
(57) **ABSTRACT**

A needle assembly for an injection device comprising a needle cannula which is mounted in a hub connectable to an injection device, and a biasing shield which is telescopically guided relative to the hub between a position in which the needle cannula is covered and a position in which at least the sharp end of the needle cannula is exposed, such that an injection can be performed without visual contact with the needle cannula. Further releasable locking means is provided such that the user can lock or unlock the shield to perform the telescopi-cally movement. In order to release the shield, the injection device itself can be utilized as the key for unlocking.

10 Claims, 24 Drawing Sheets



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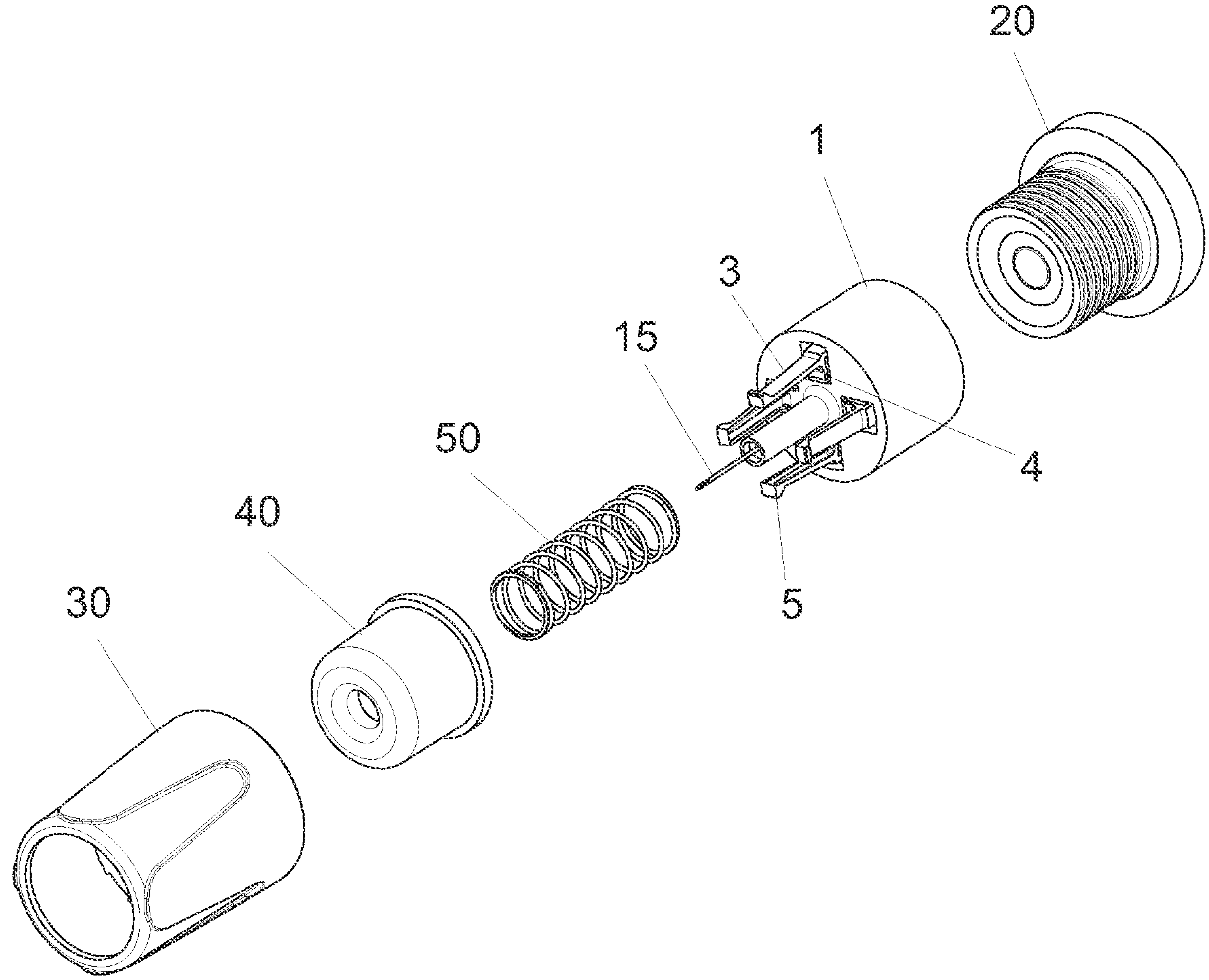


Fig. 1

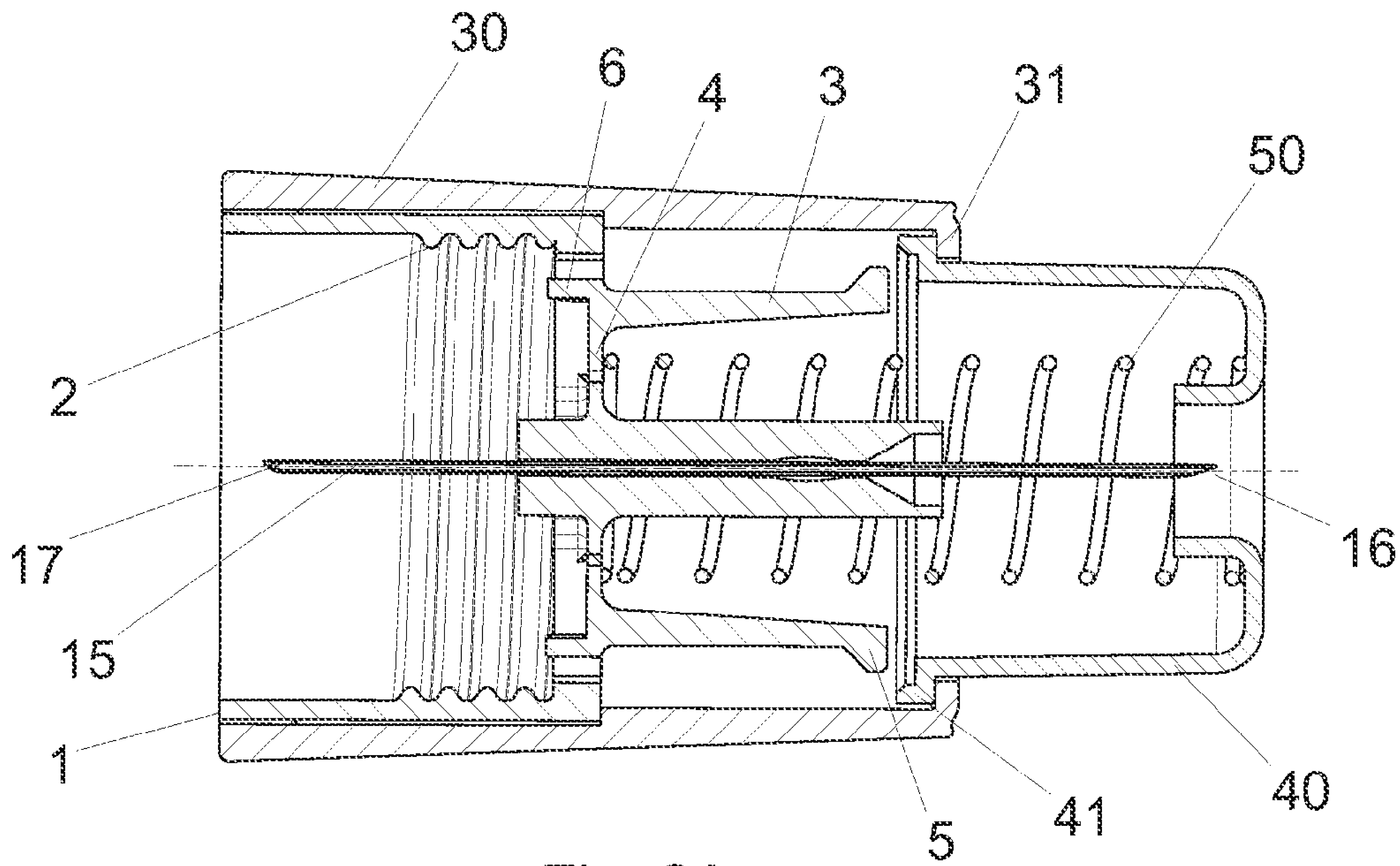


Fig. 2A

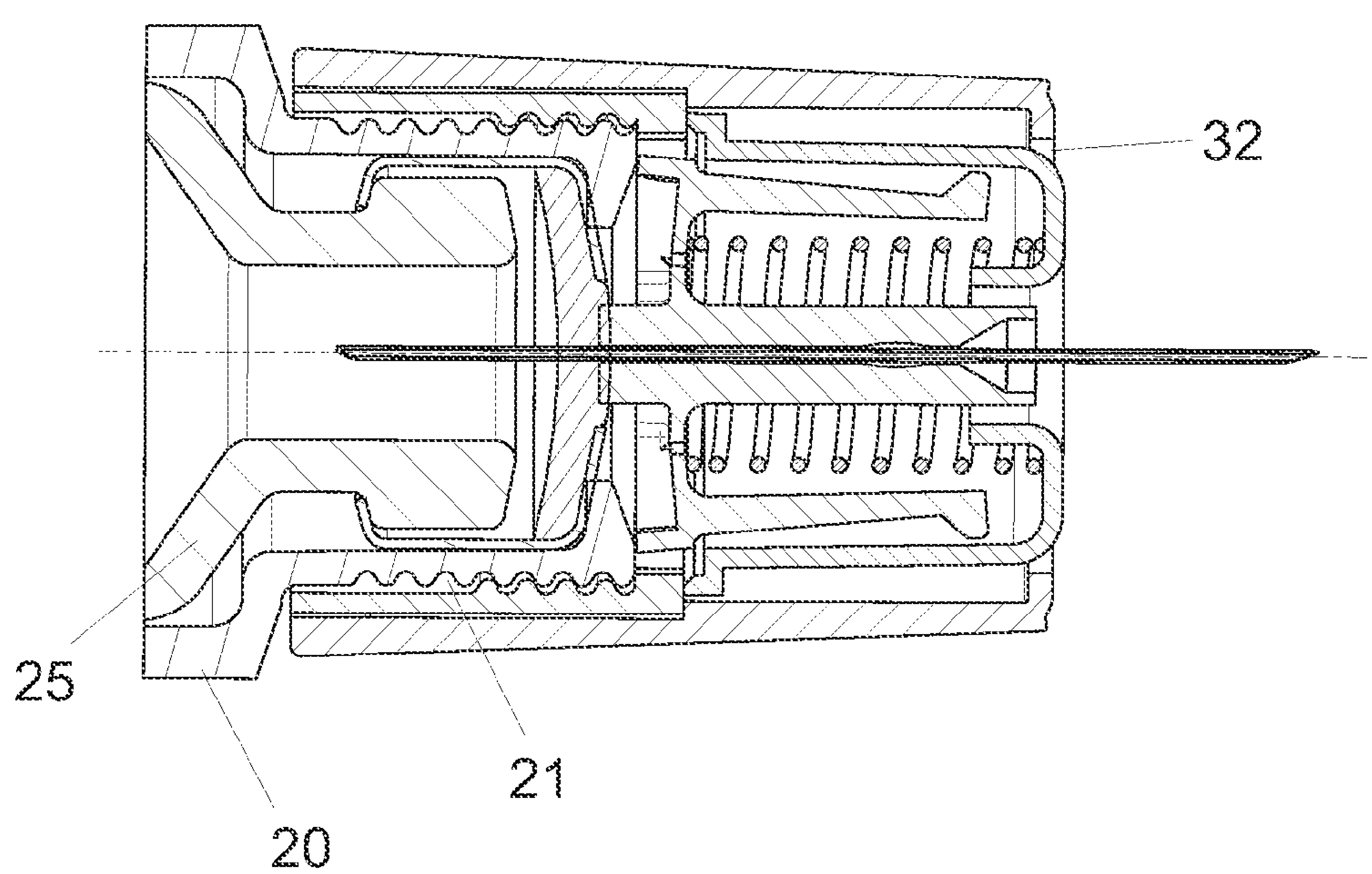
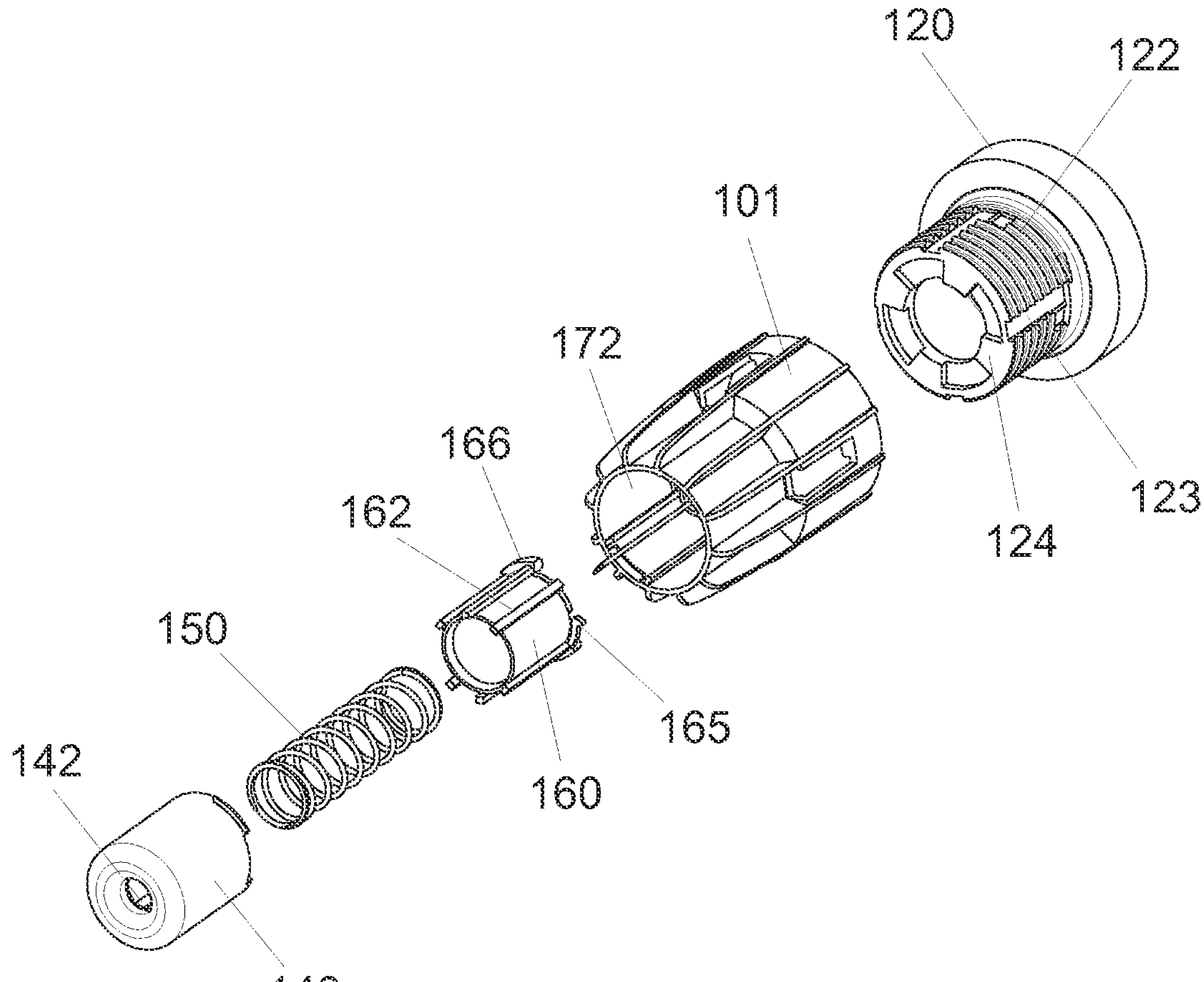


Fig. 2B



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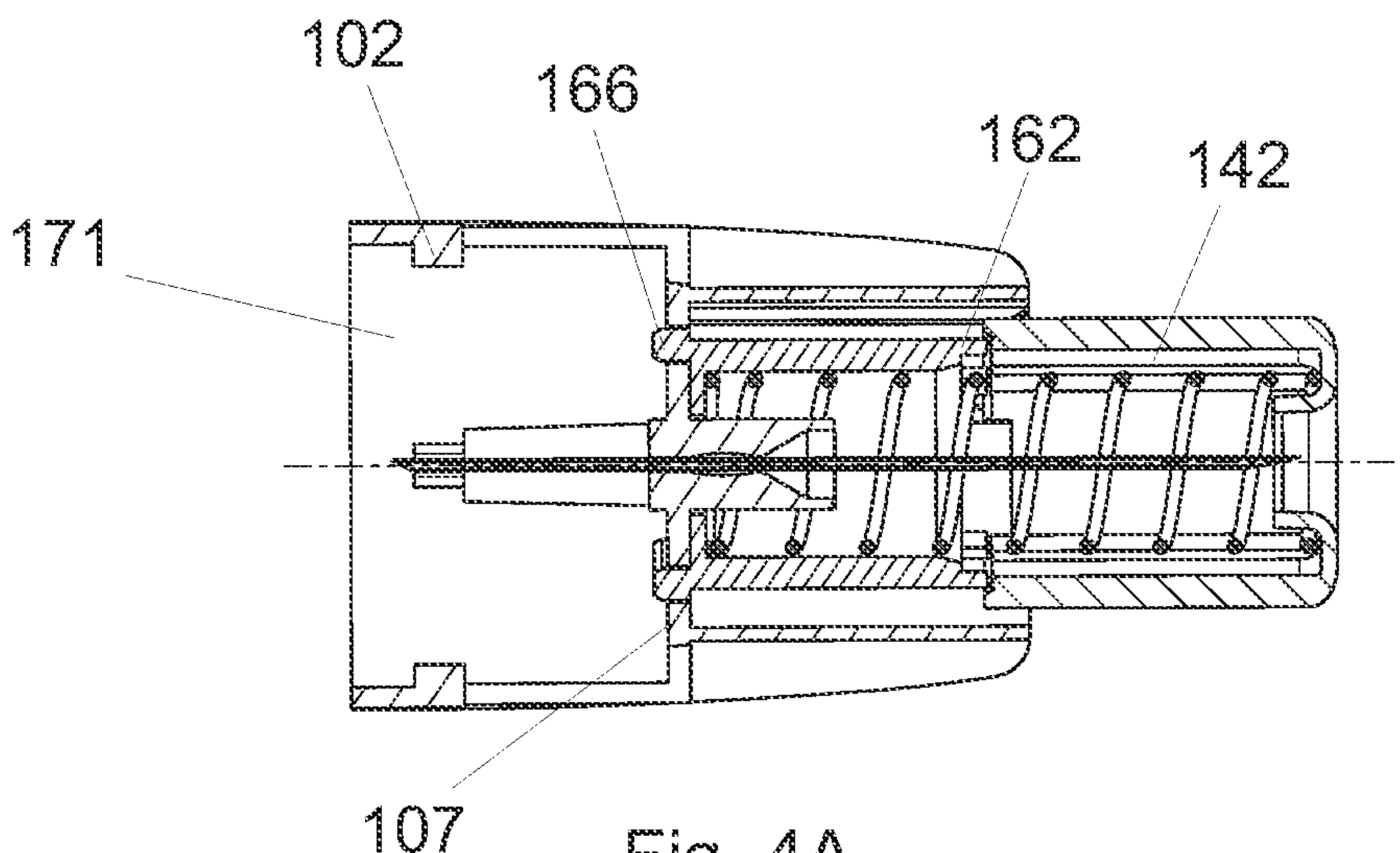


Fig. 4A

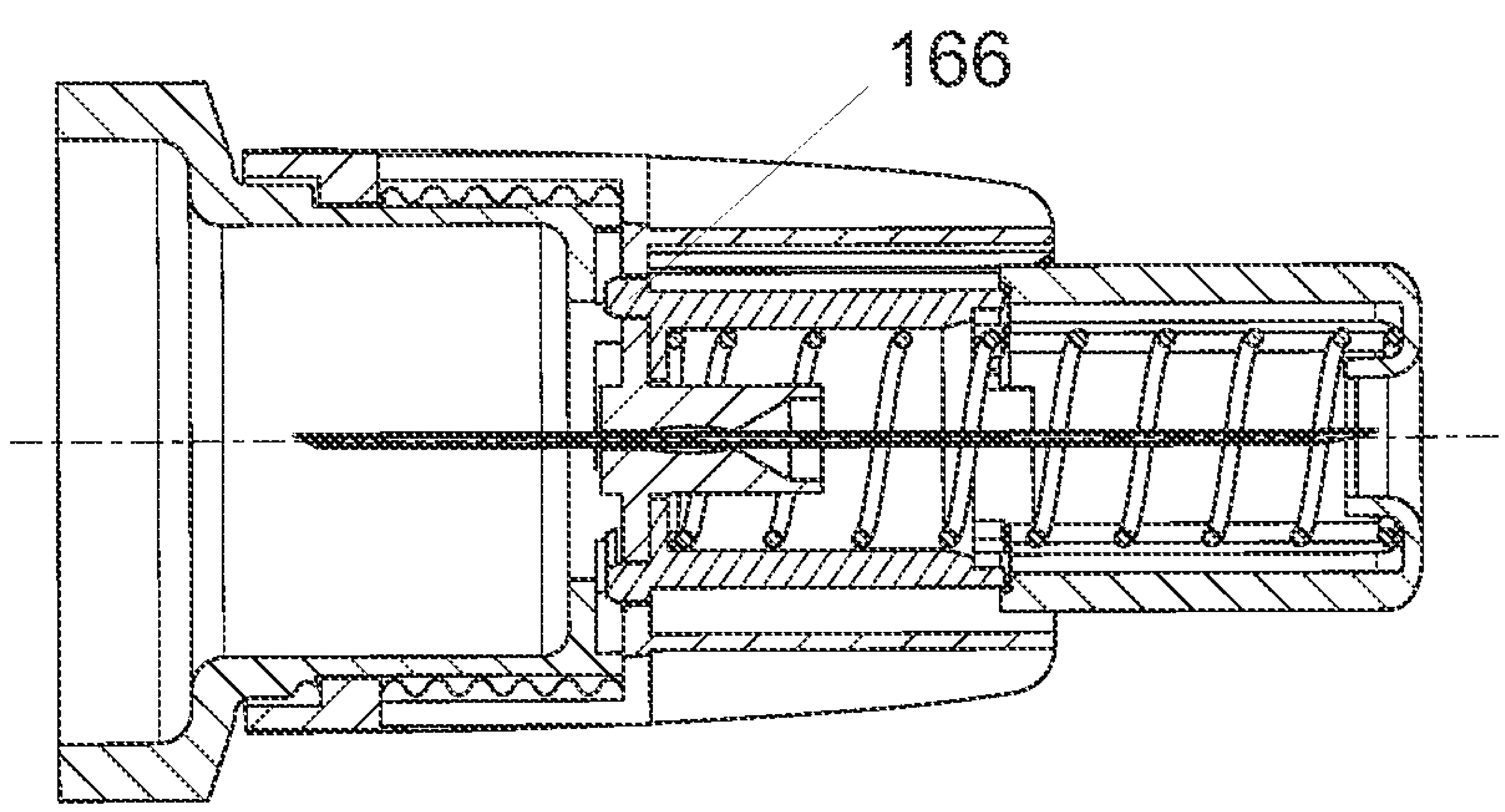


Fig. 4B

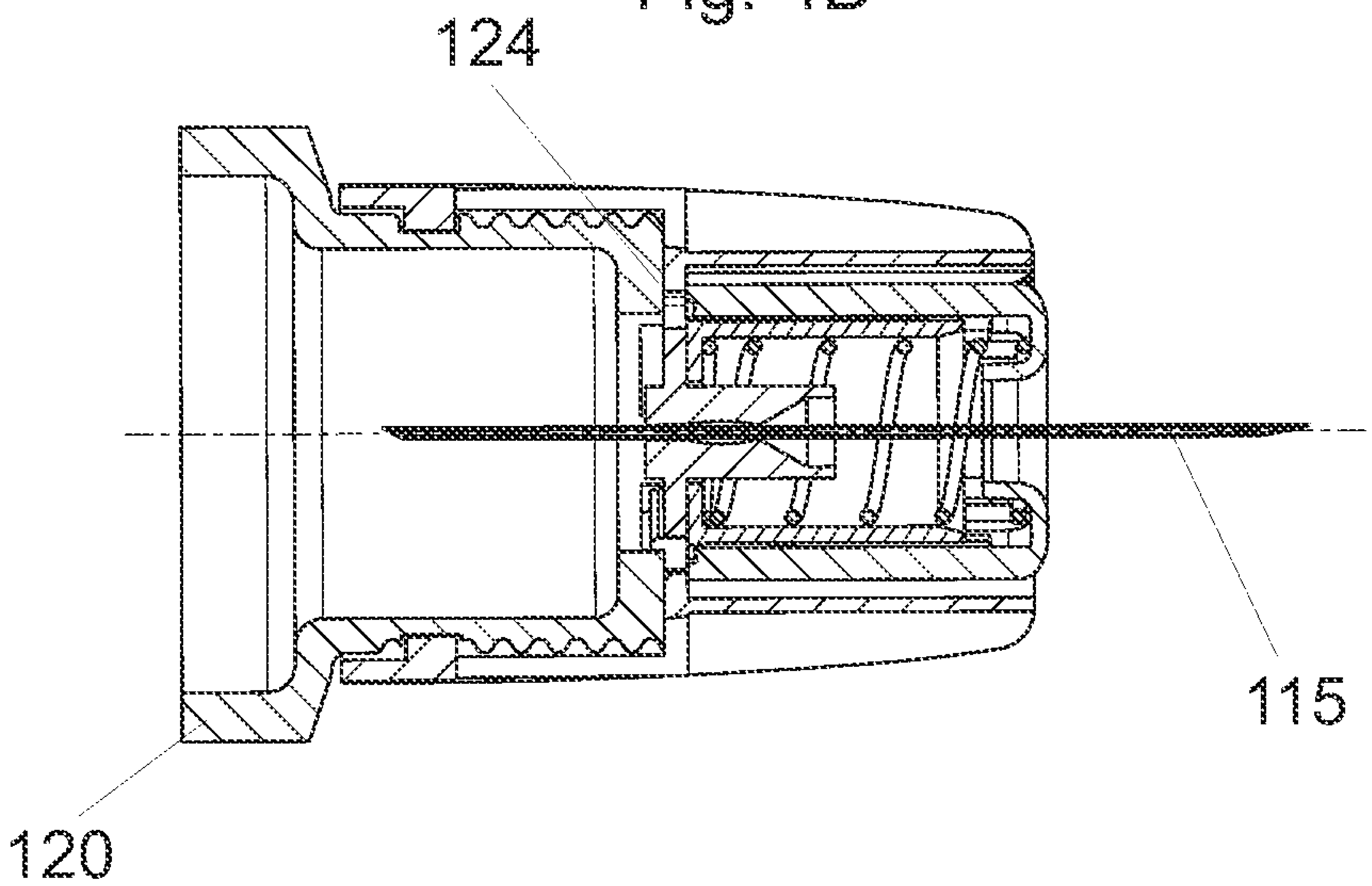
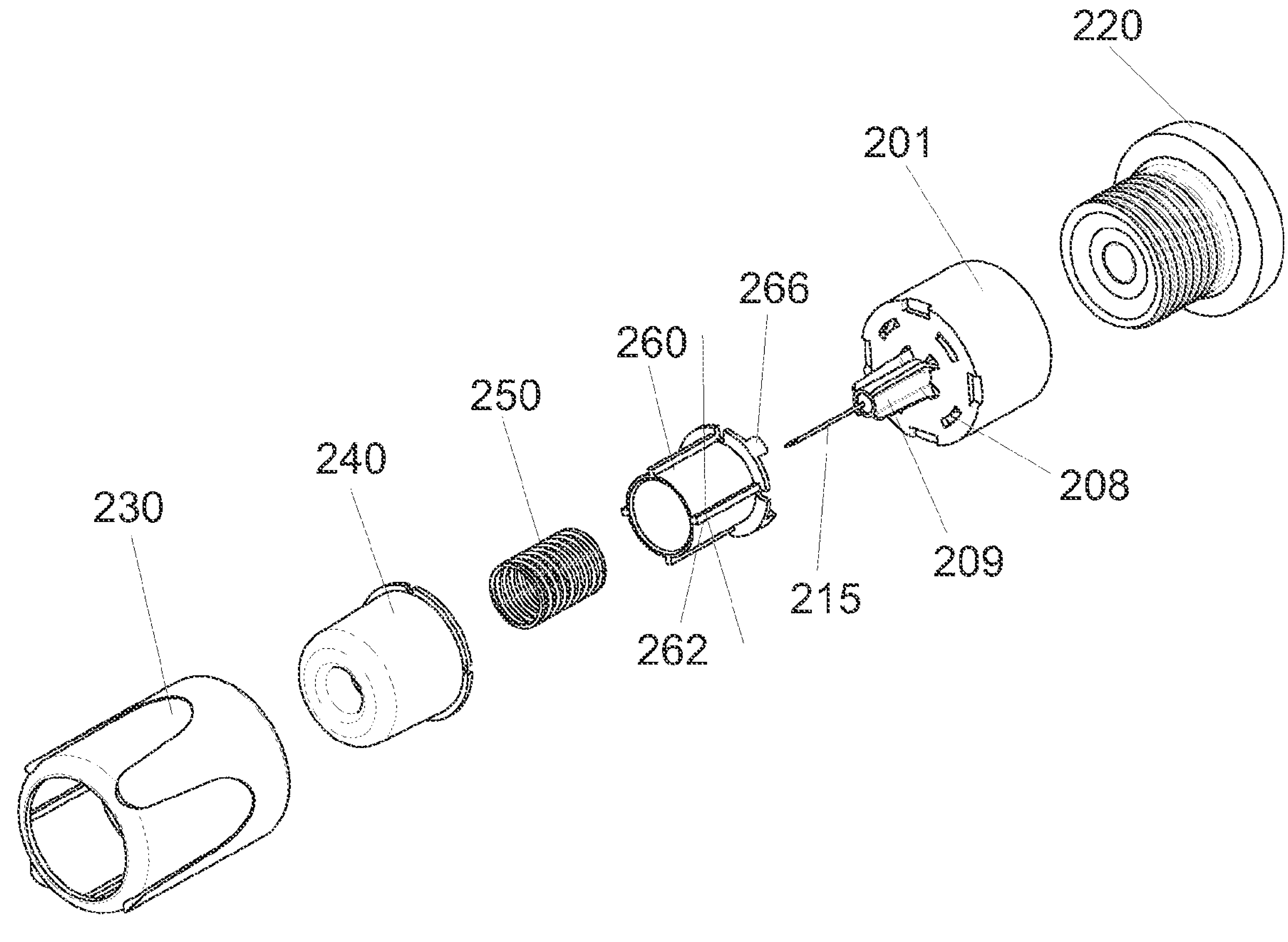


Fig 4C



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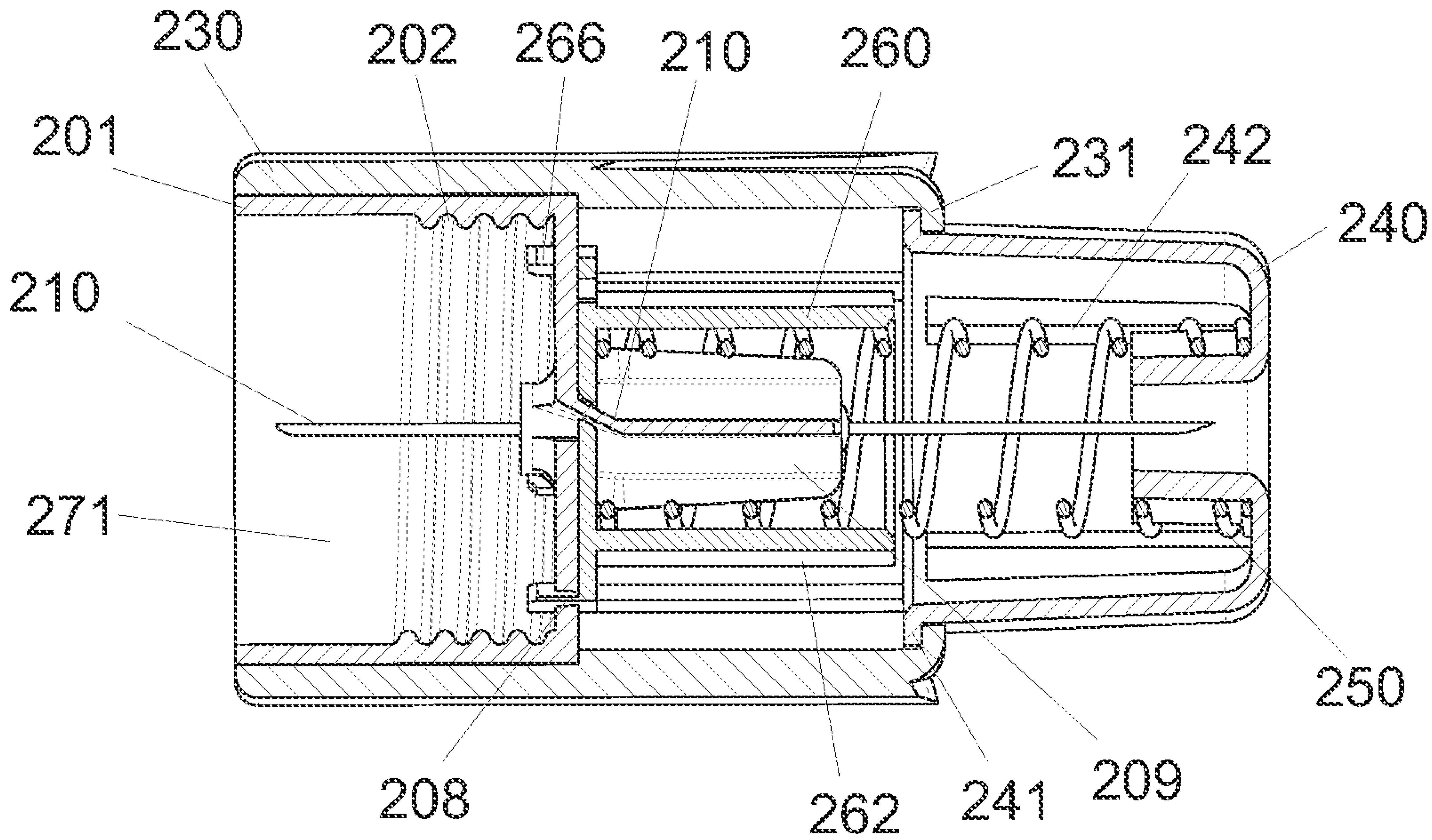

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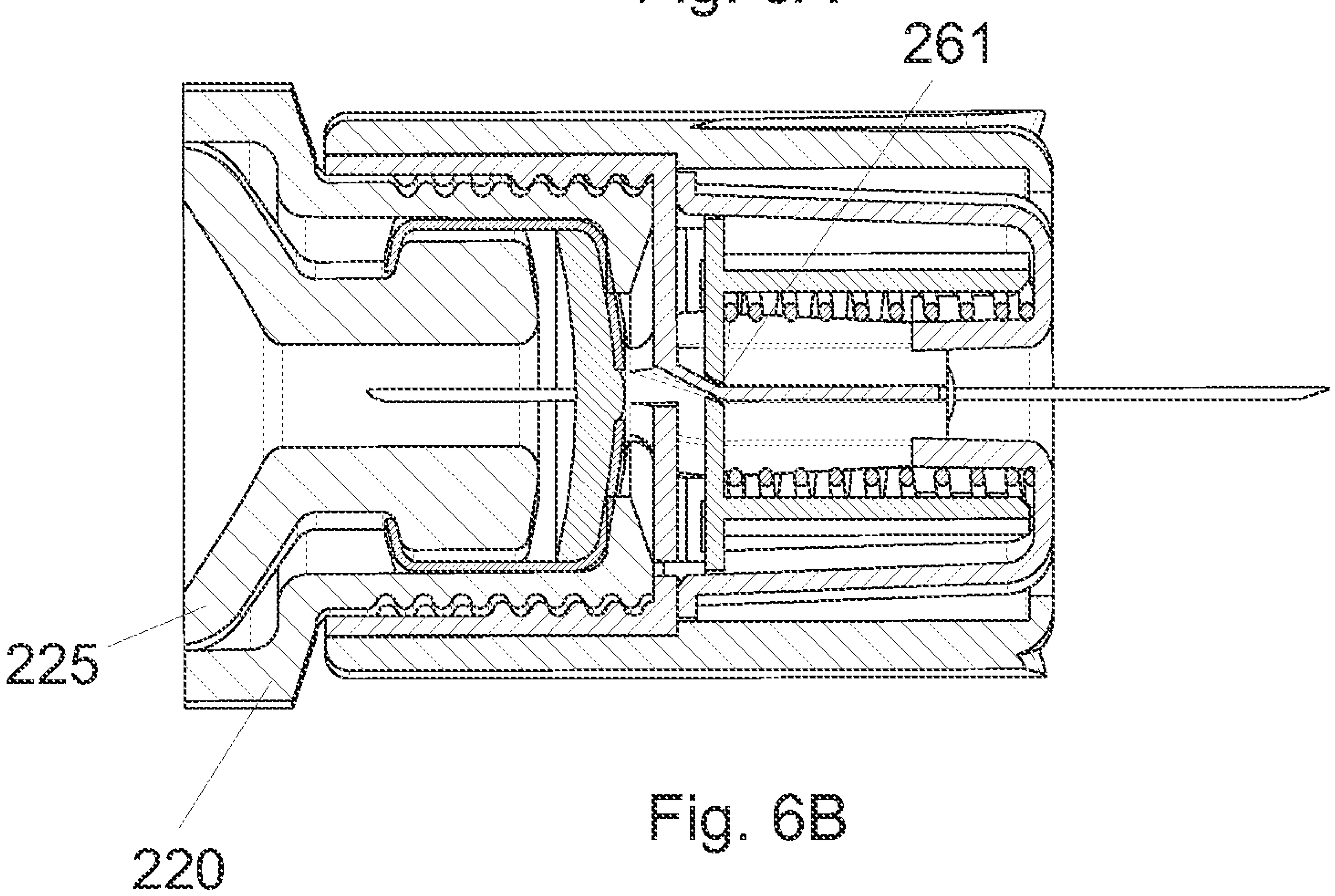
Fig. 6A



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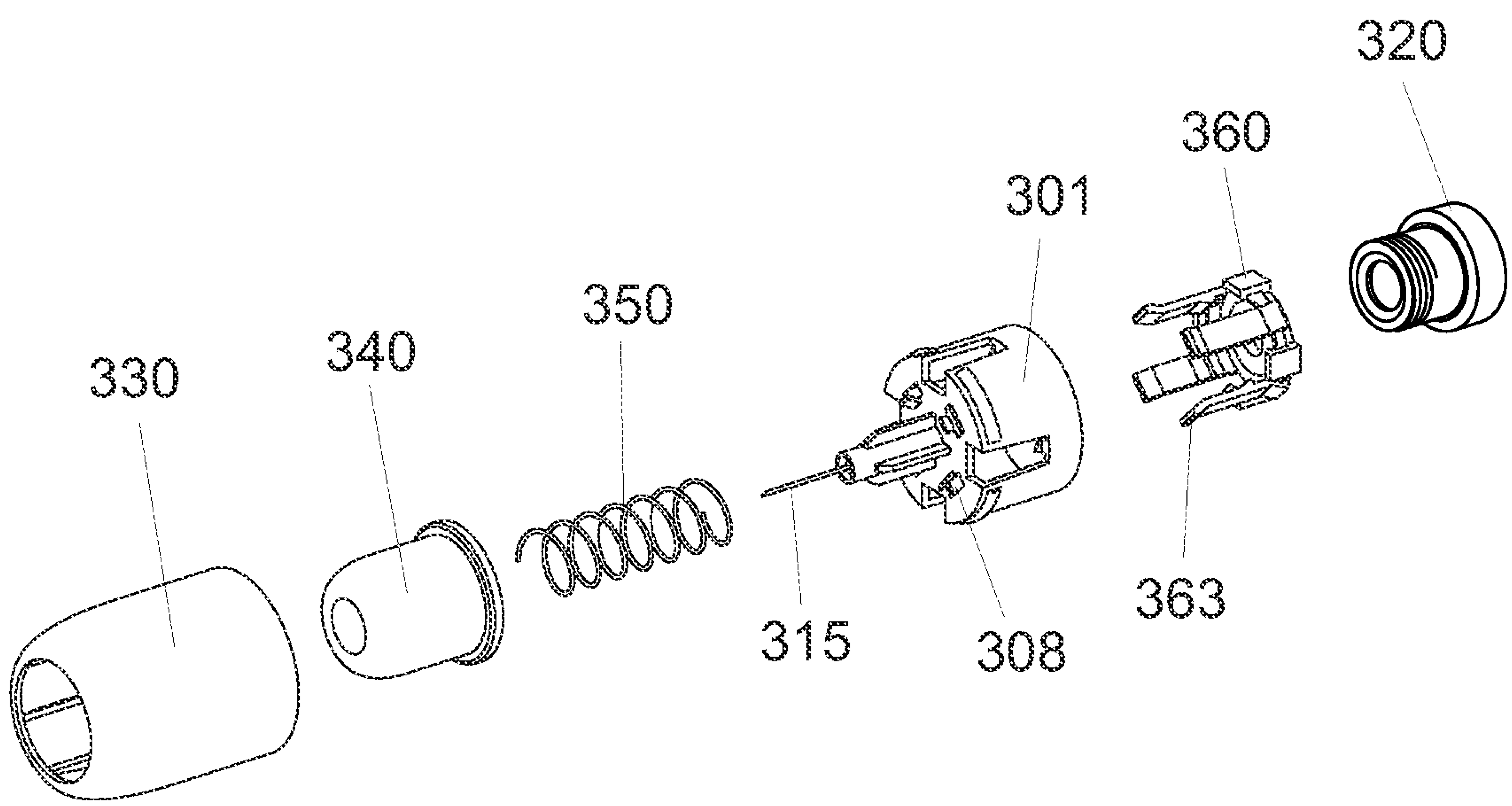

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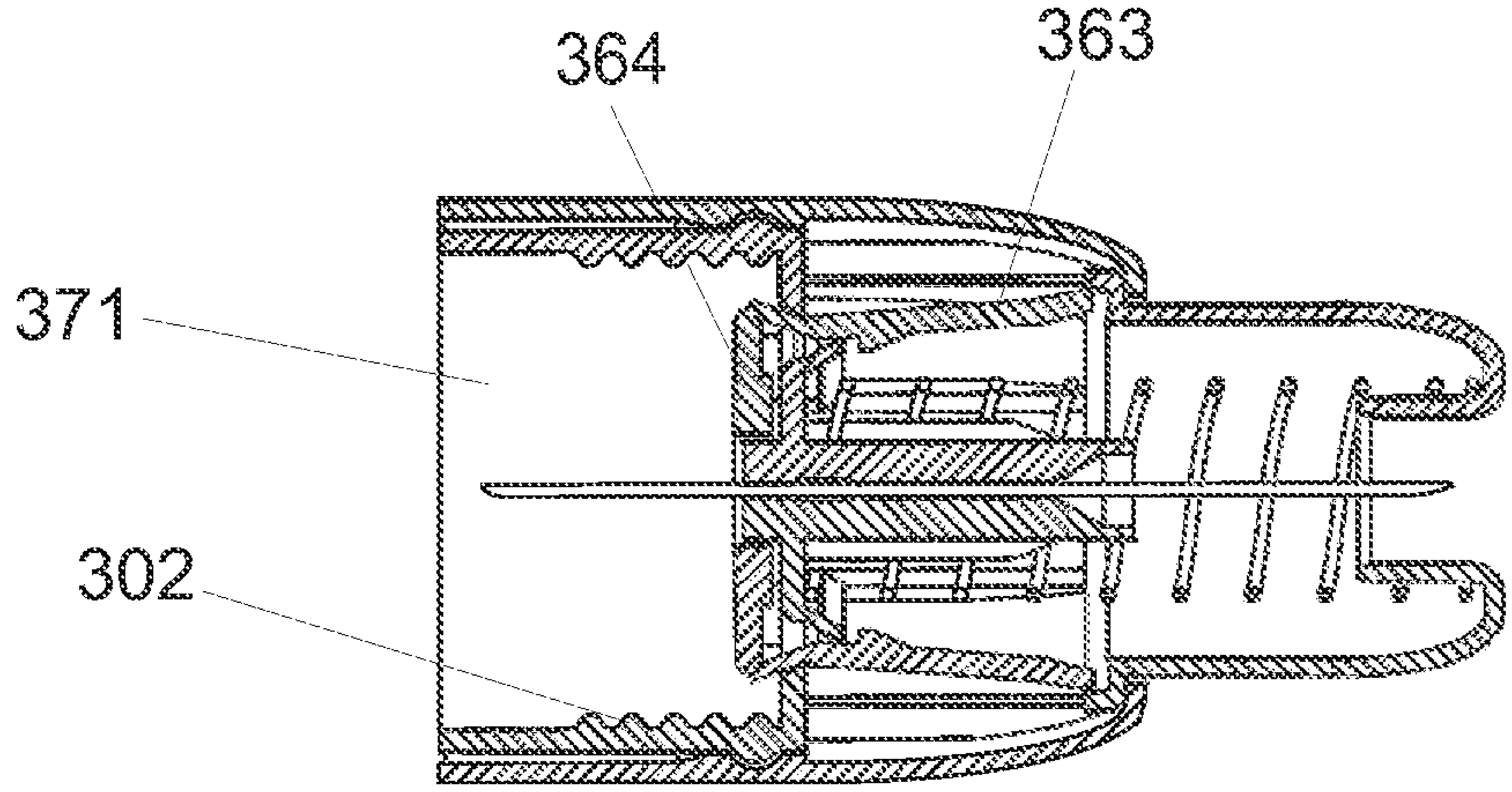

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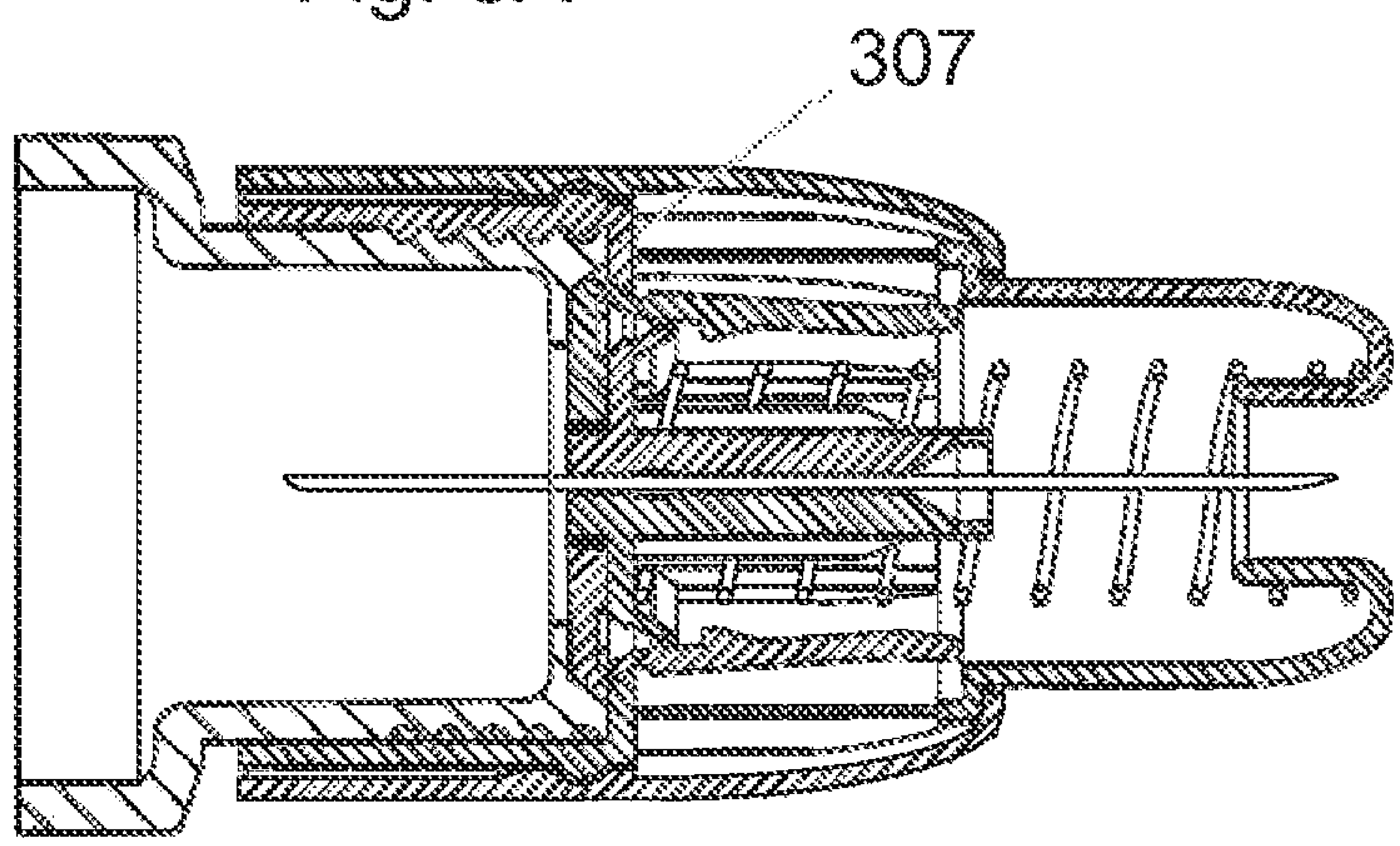
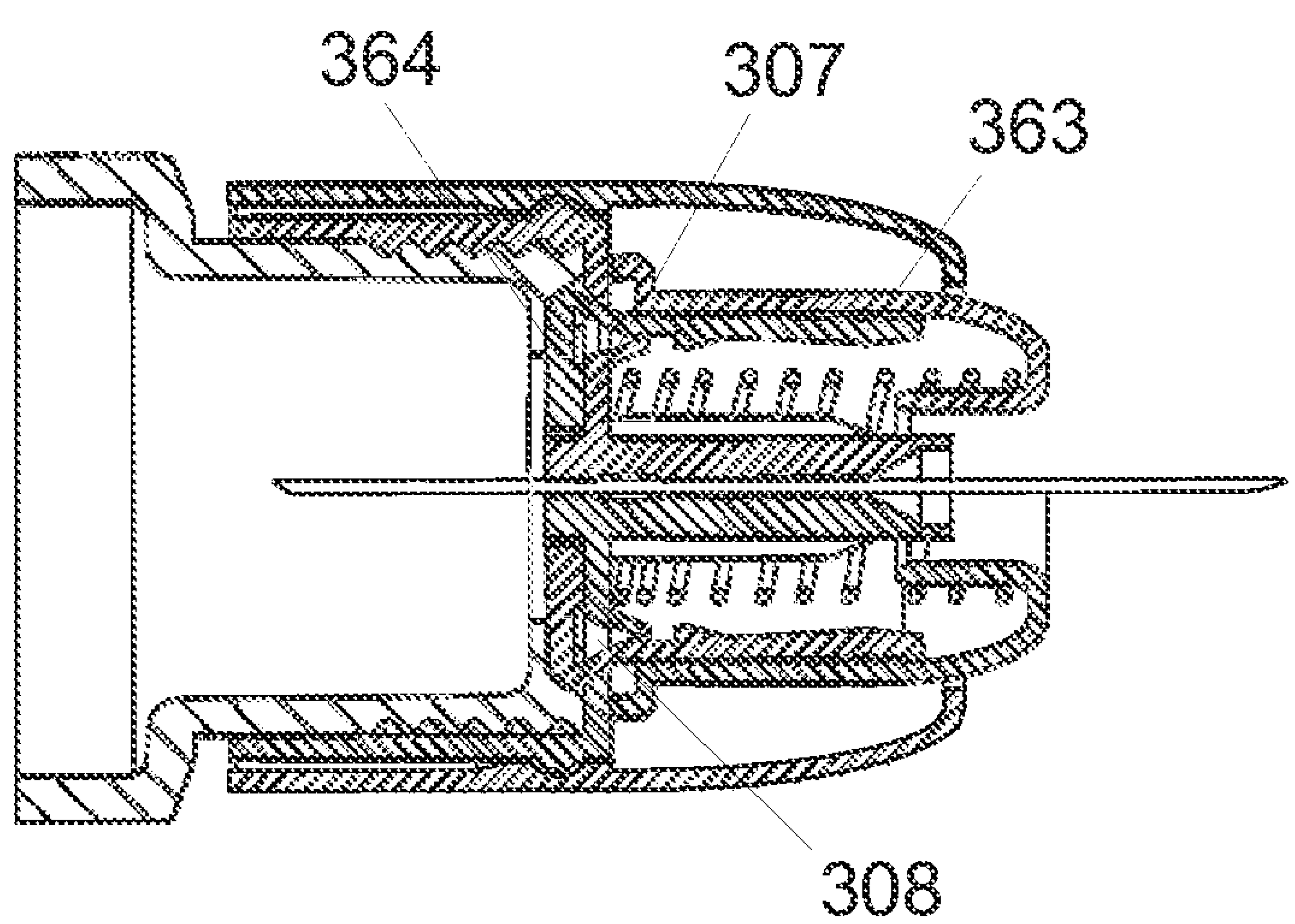


Fig 8B



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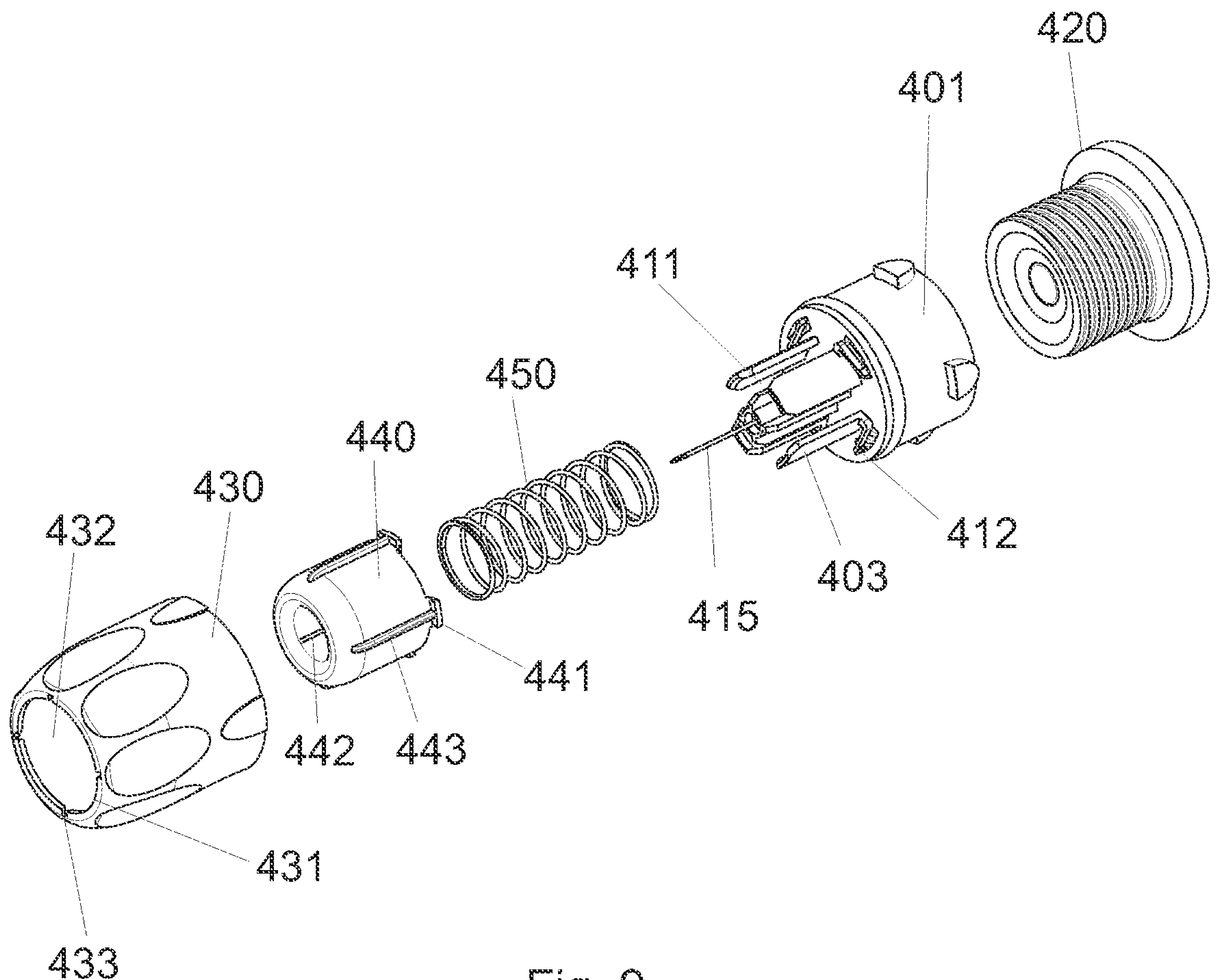

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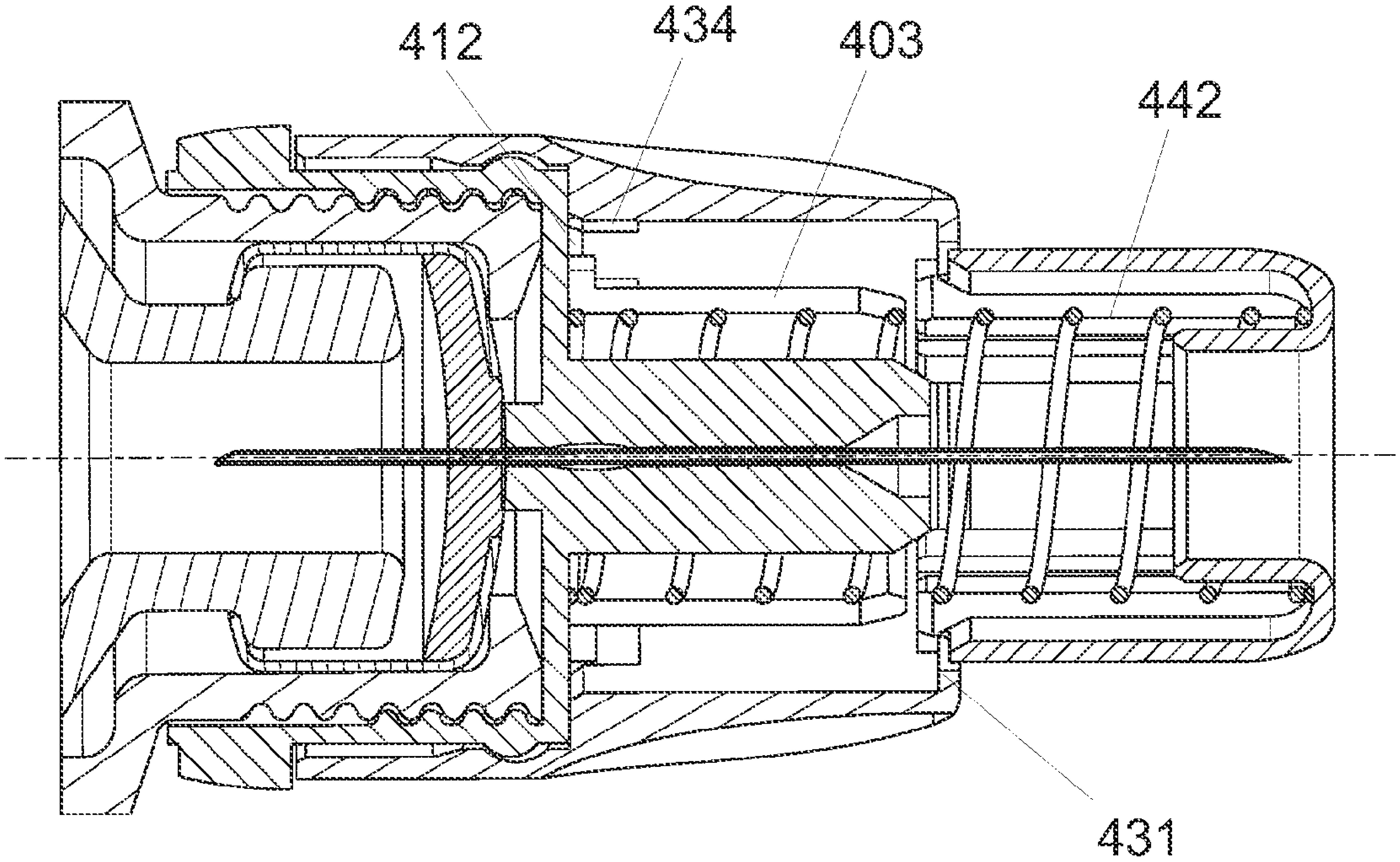

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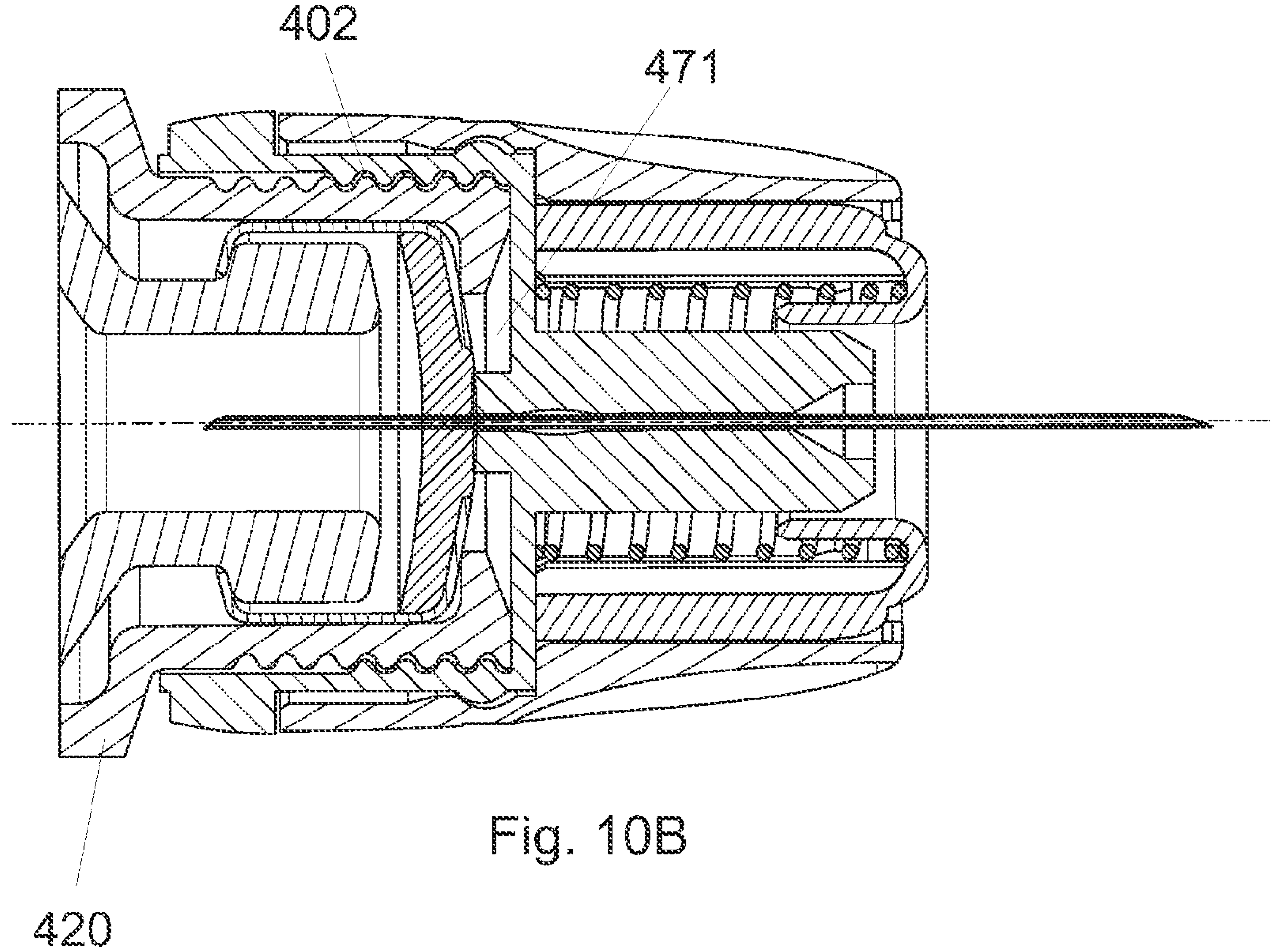

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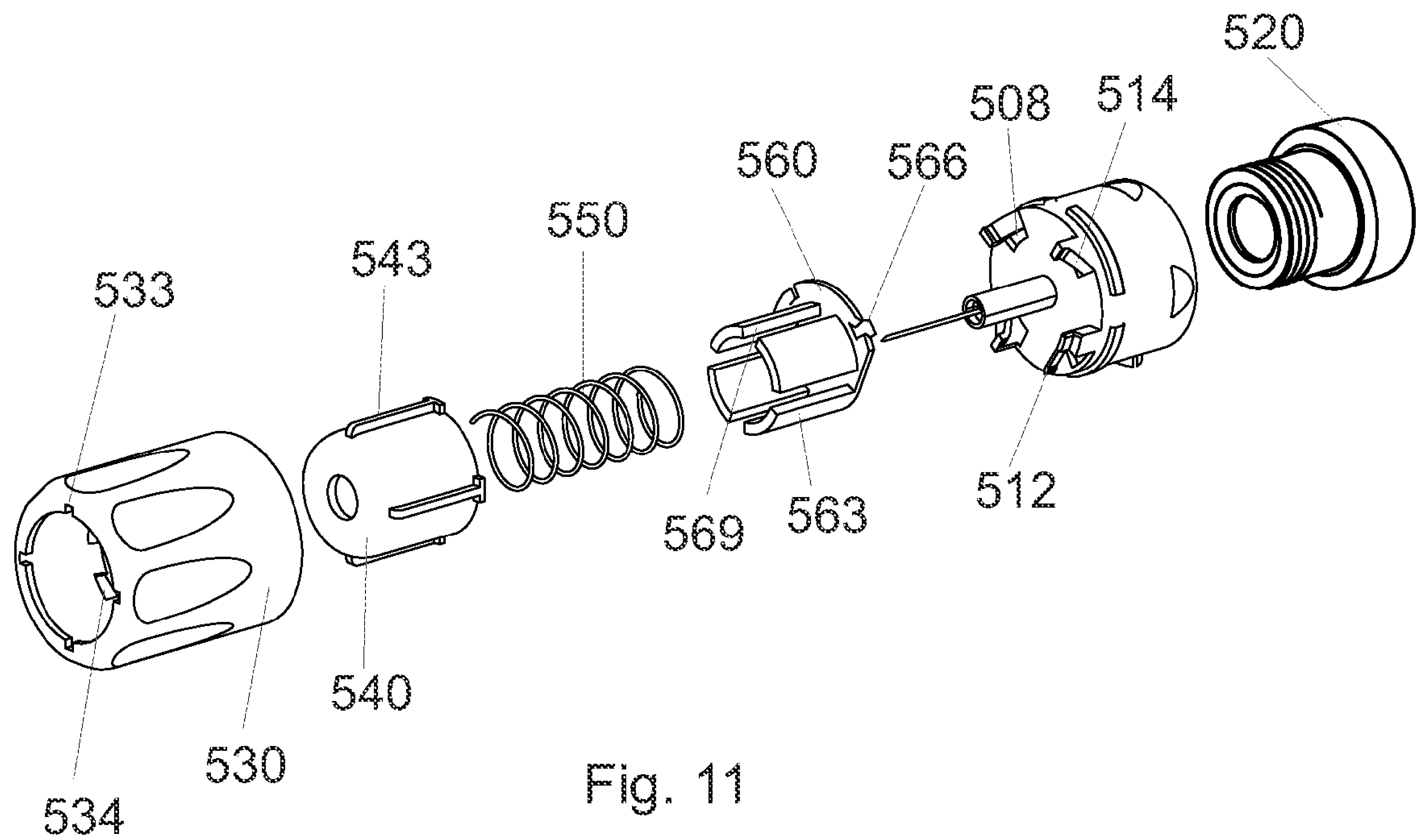
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Fig. 11

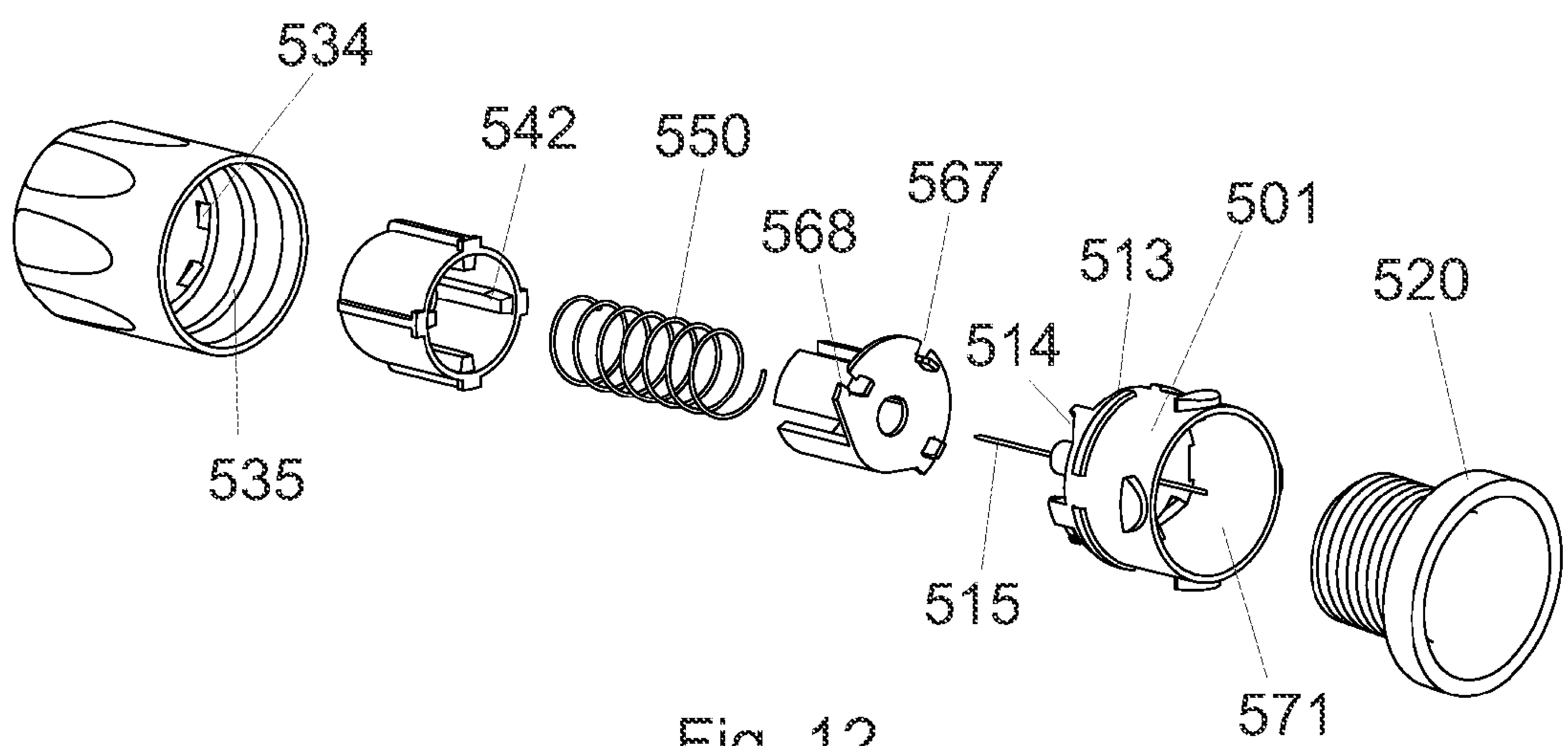
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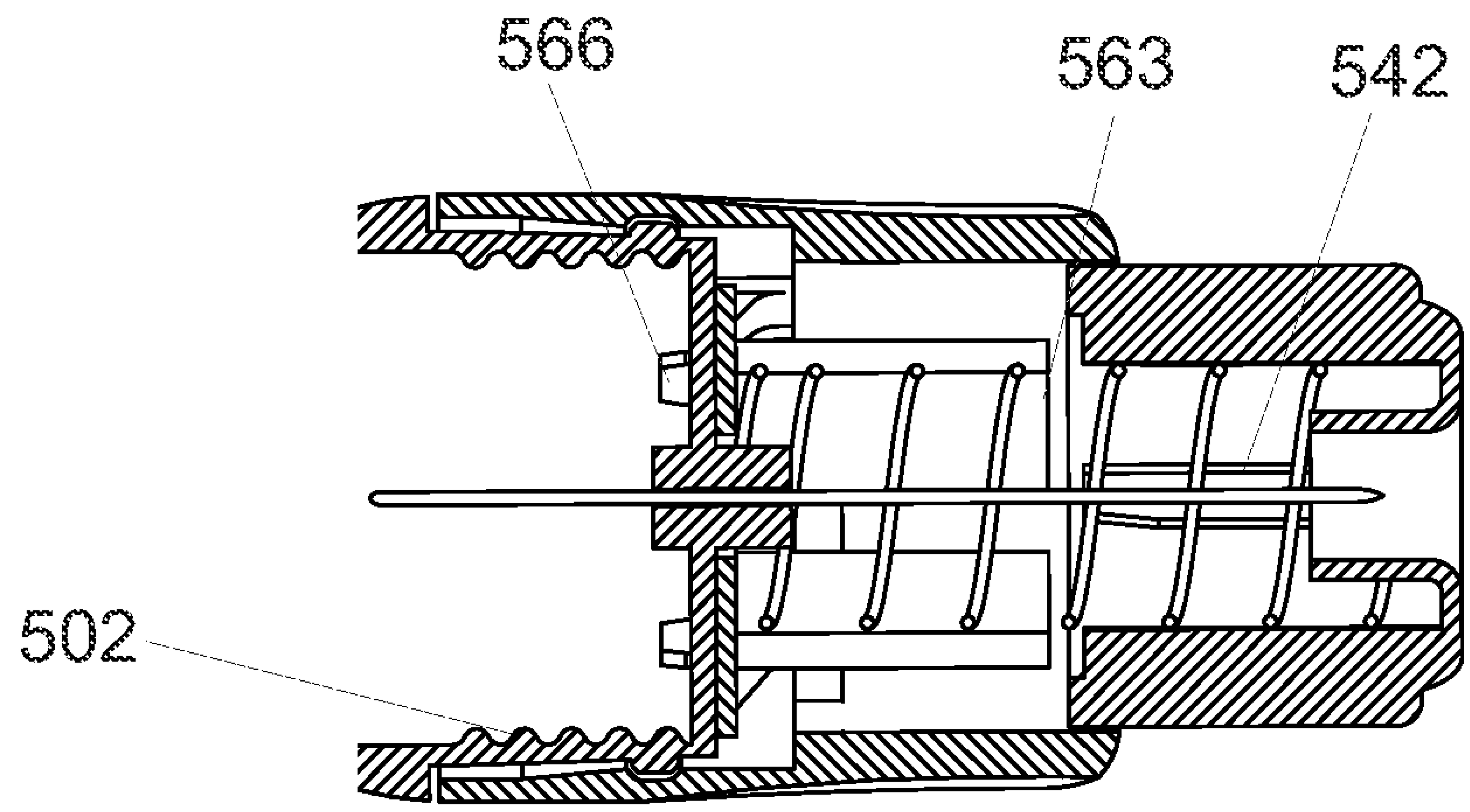
Fig. 12



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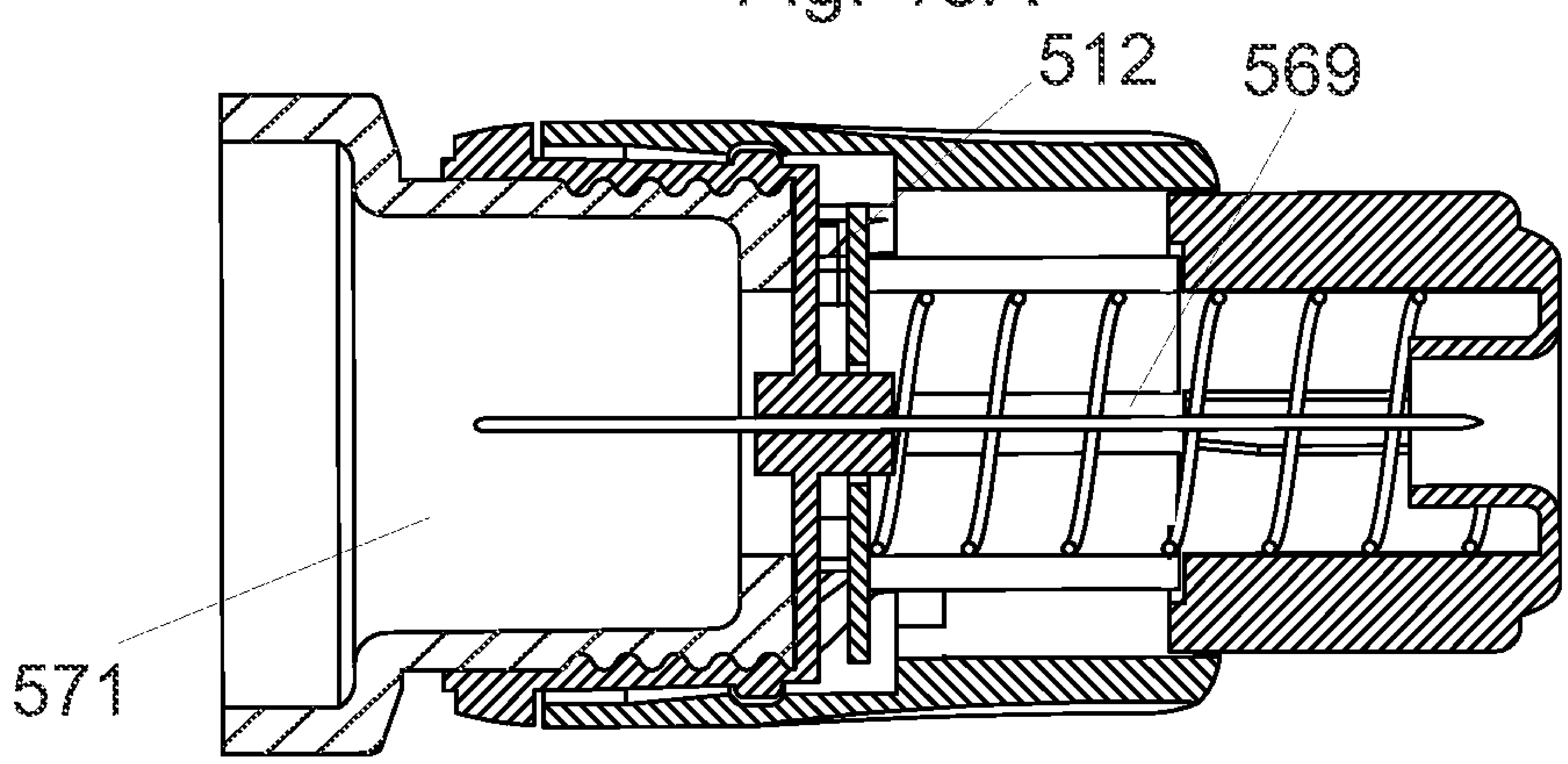

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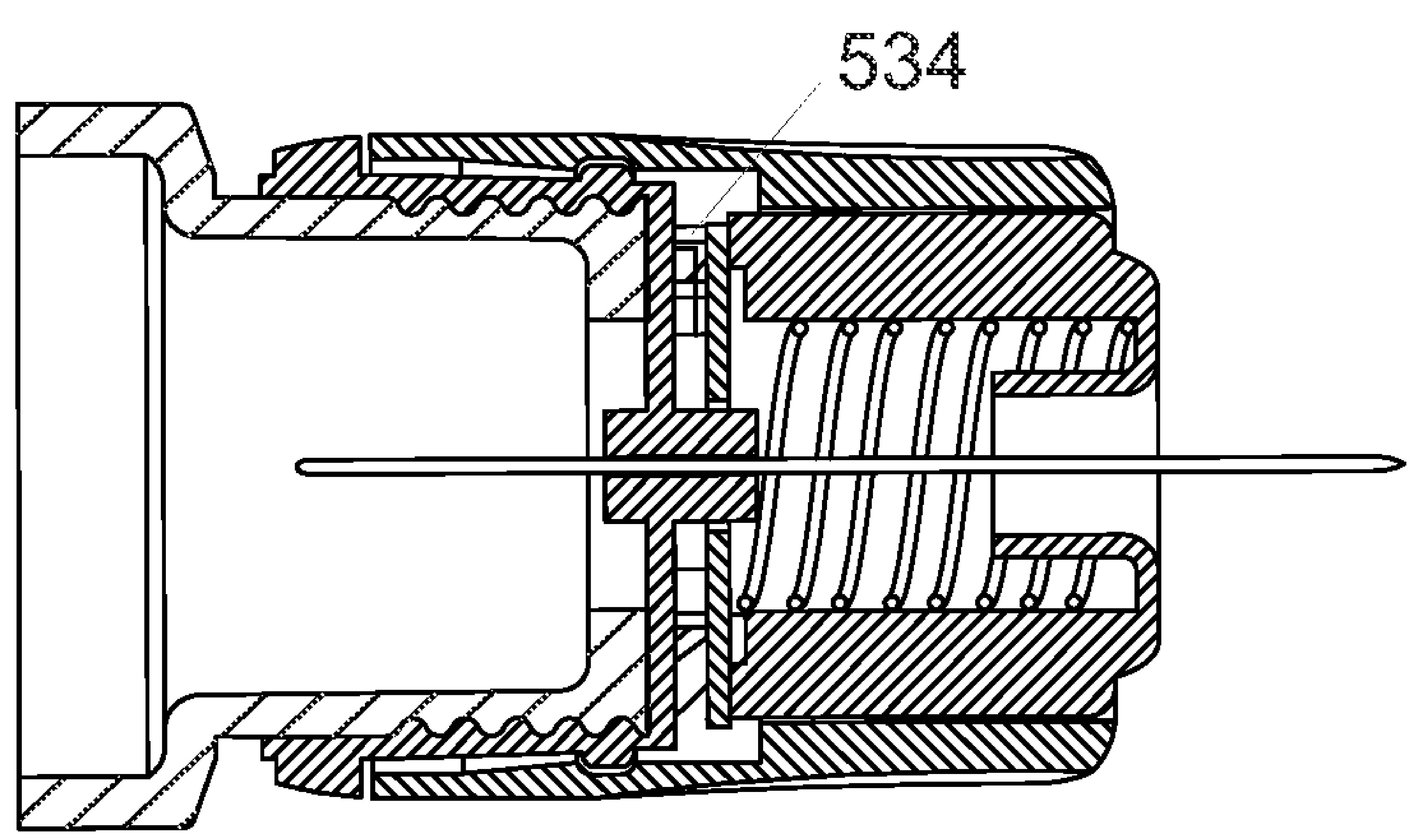

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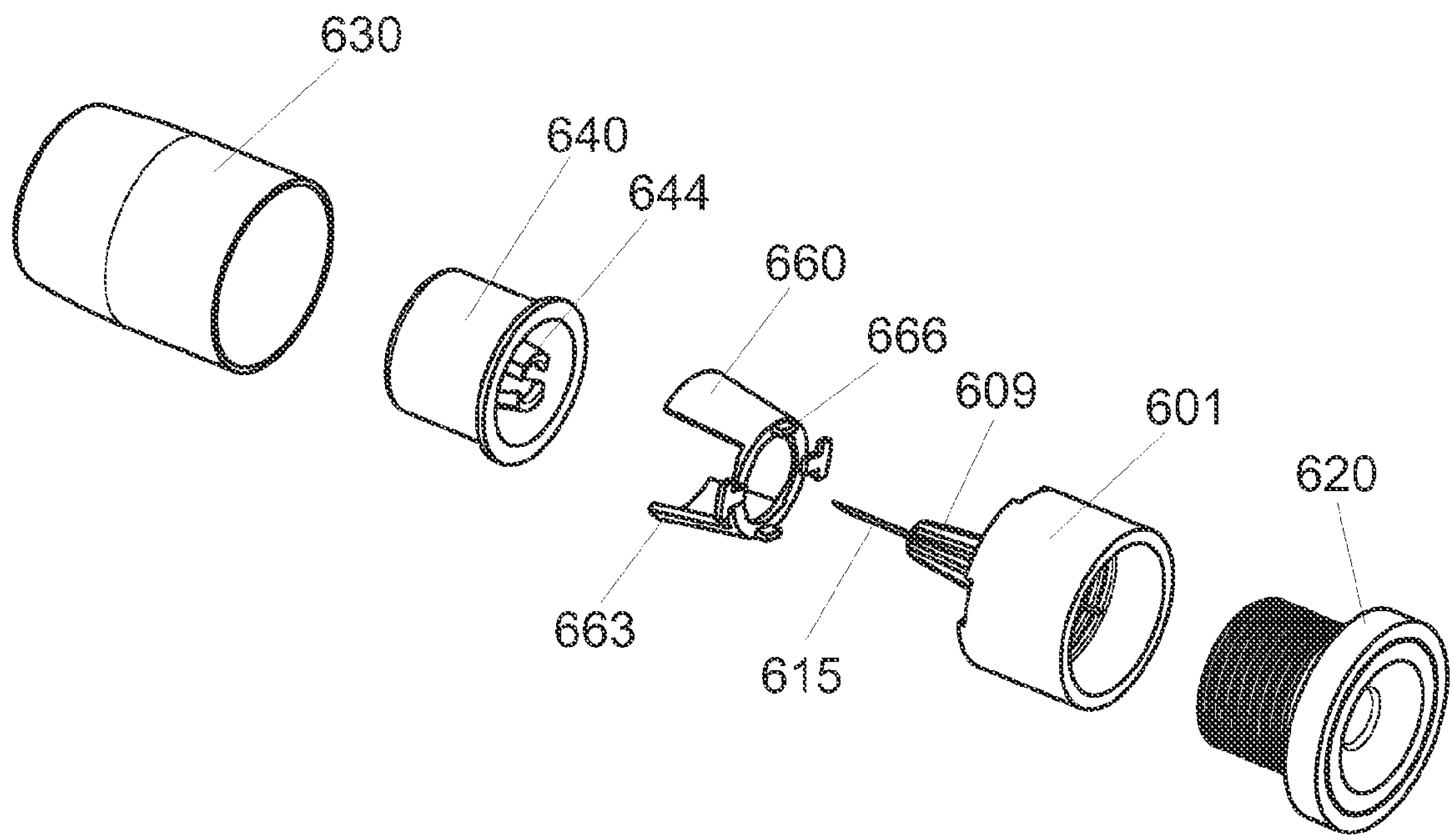
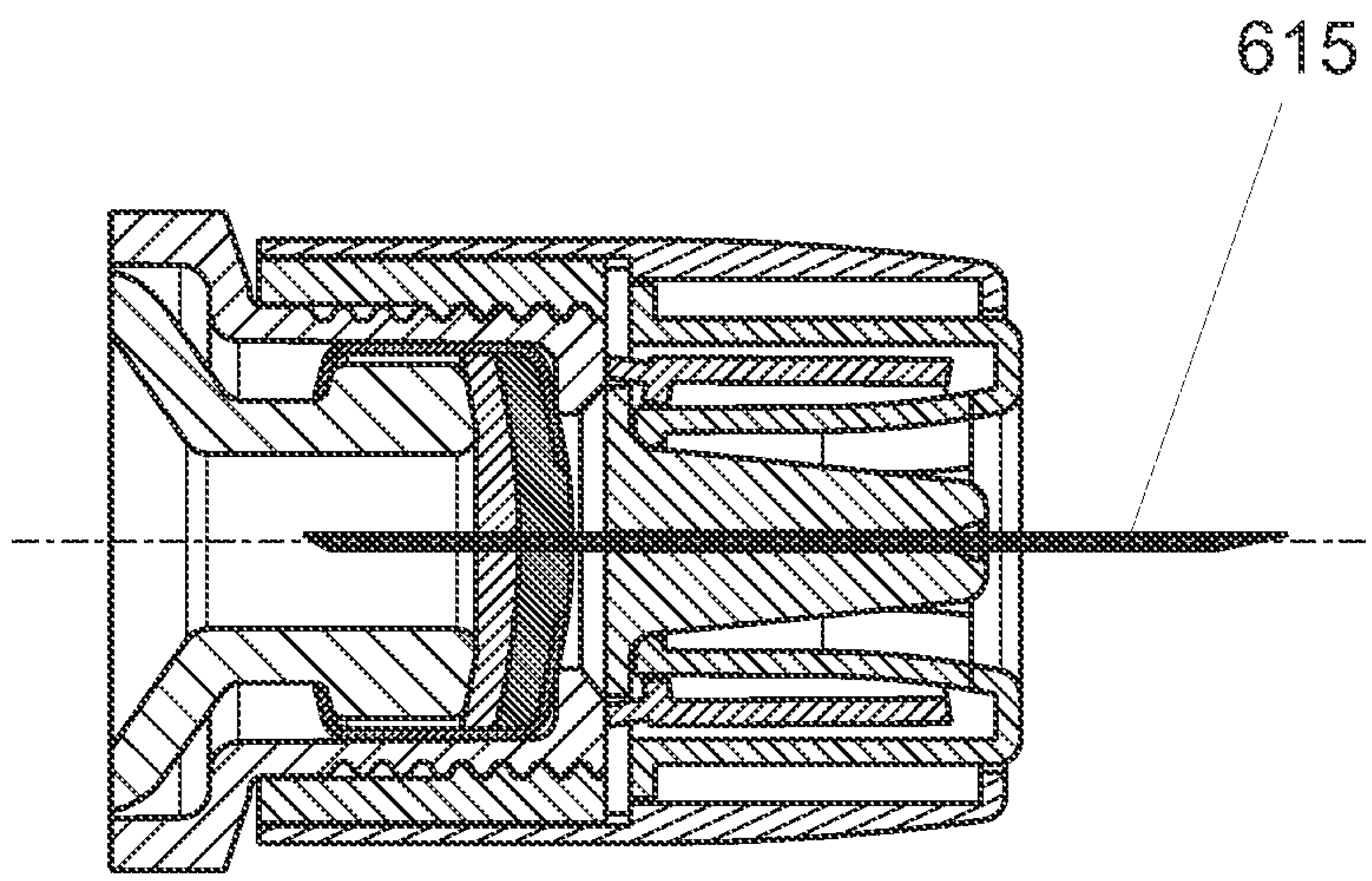


Fig. 14



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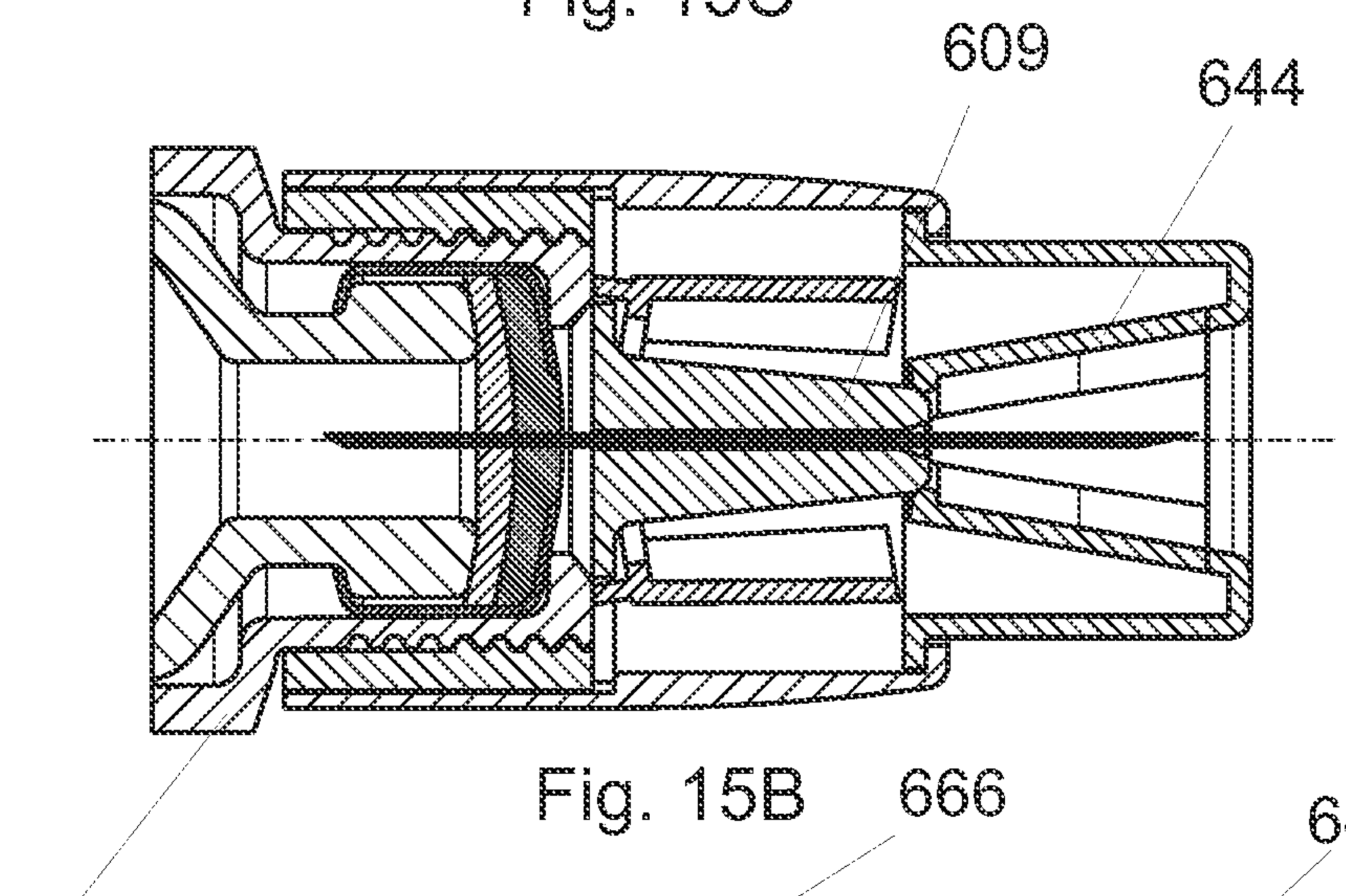

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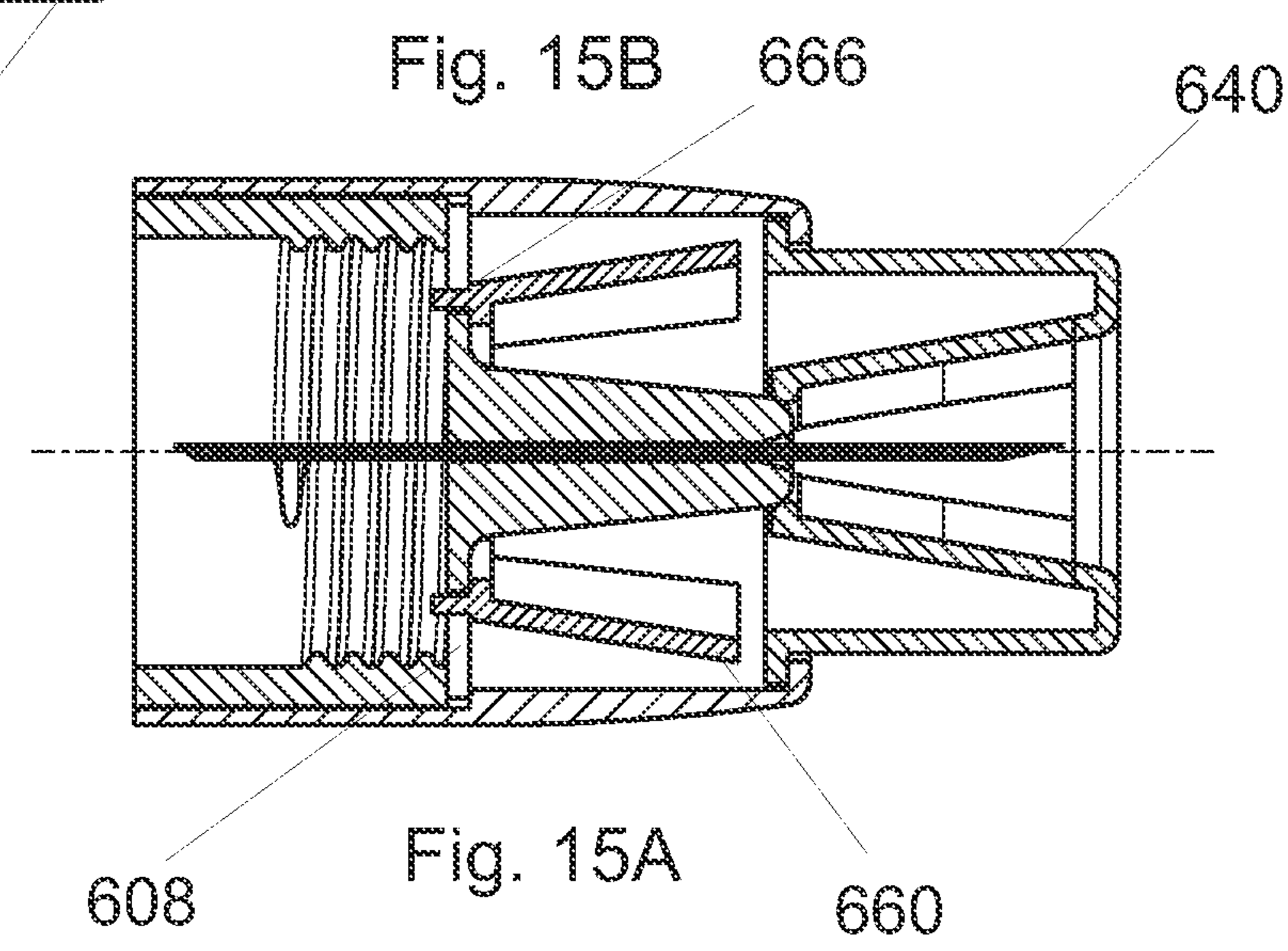

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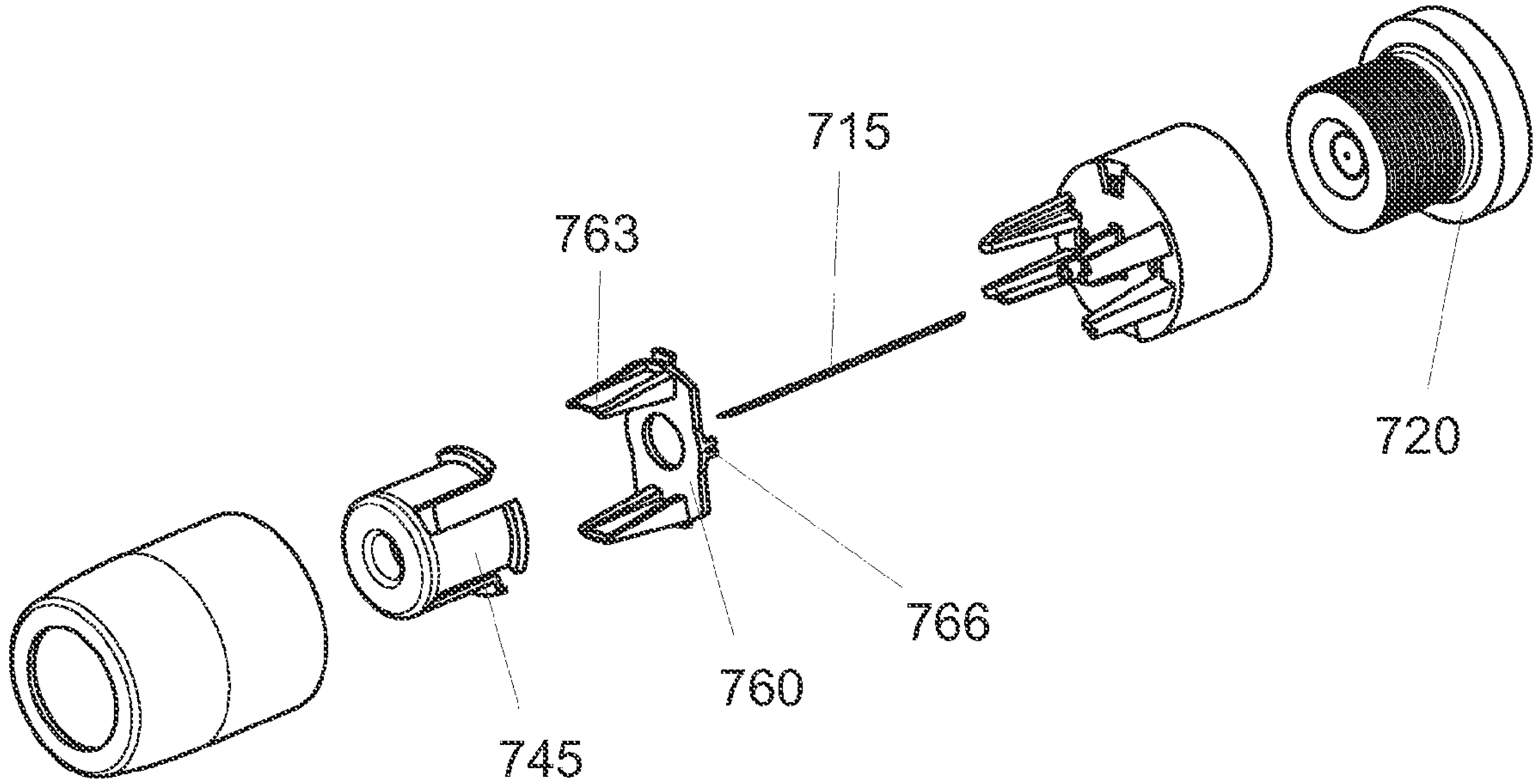

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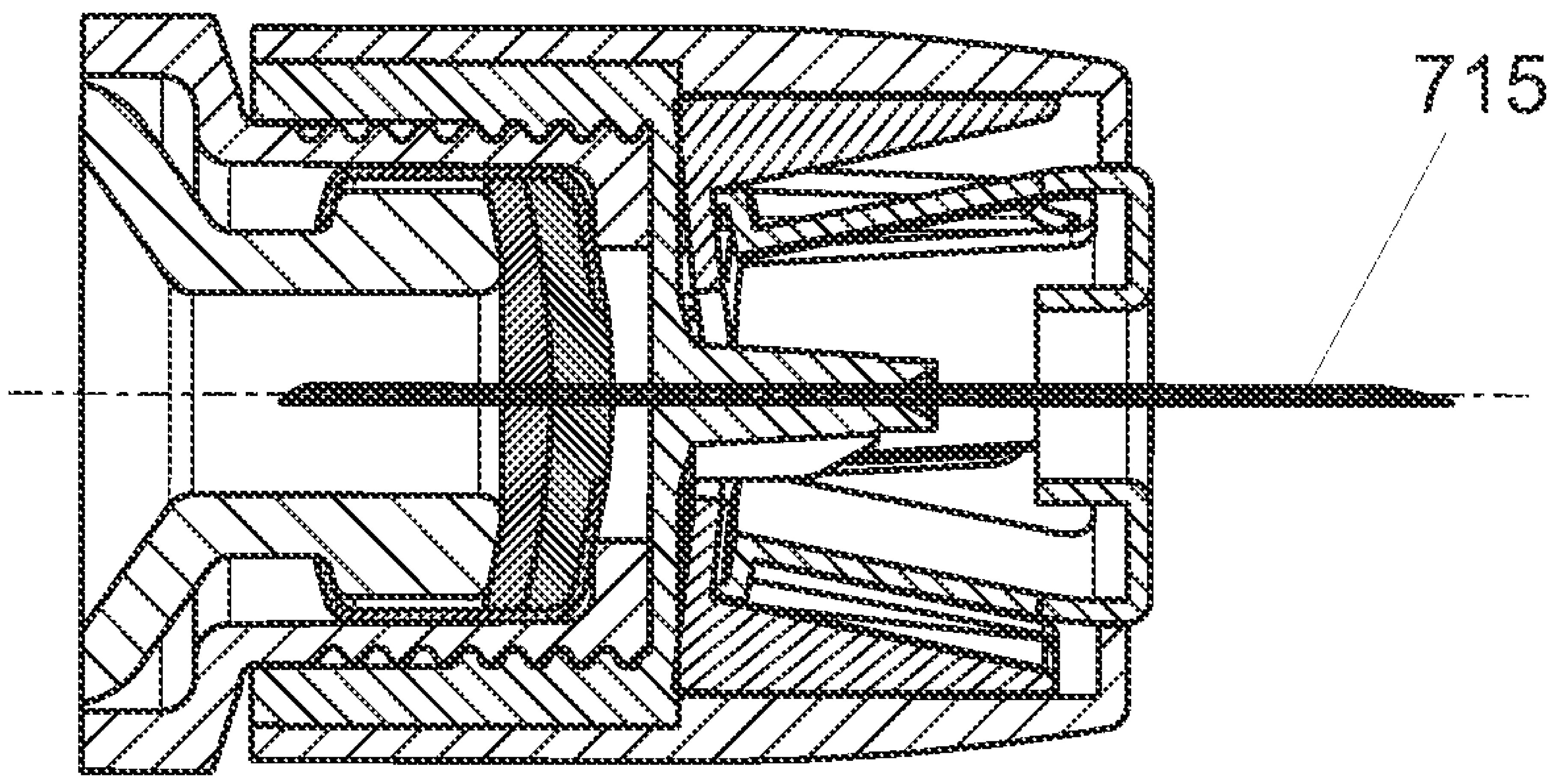

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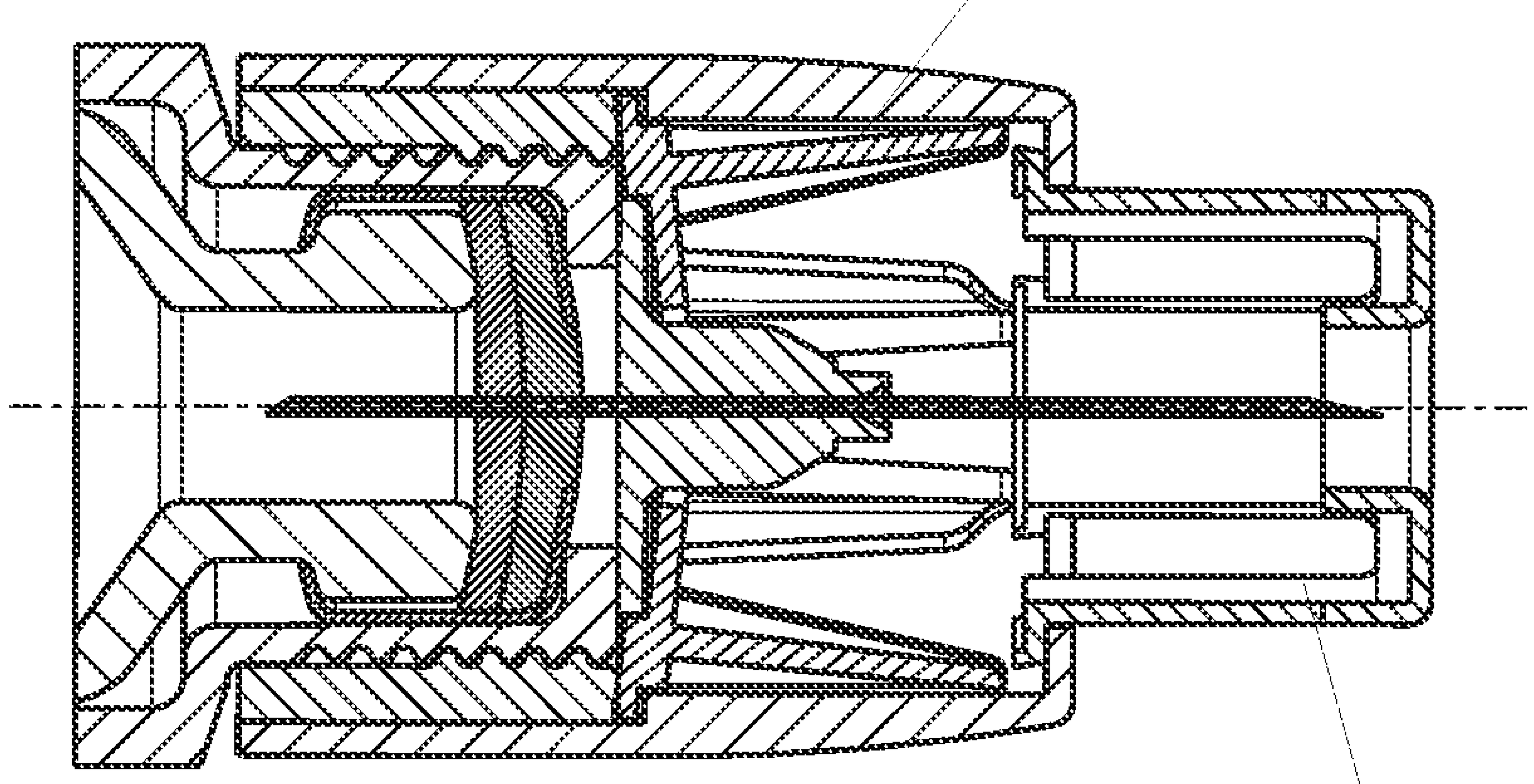

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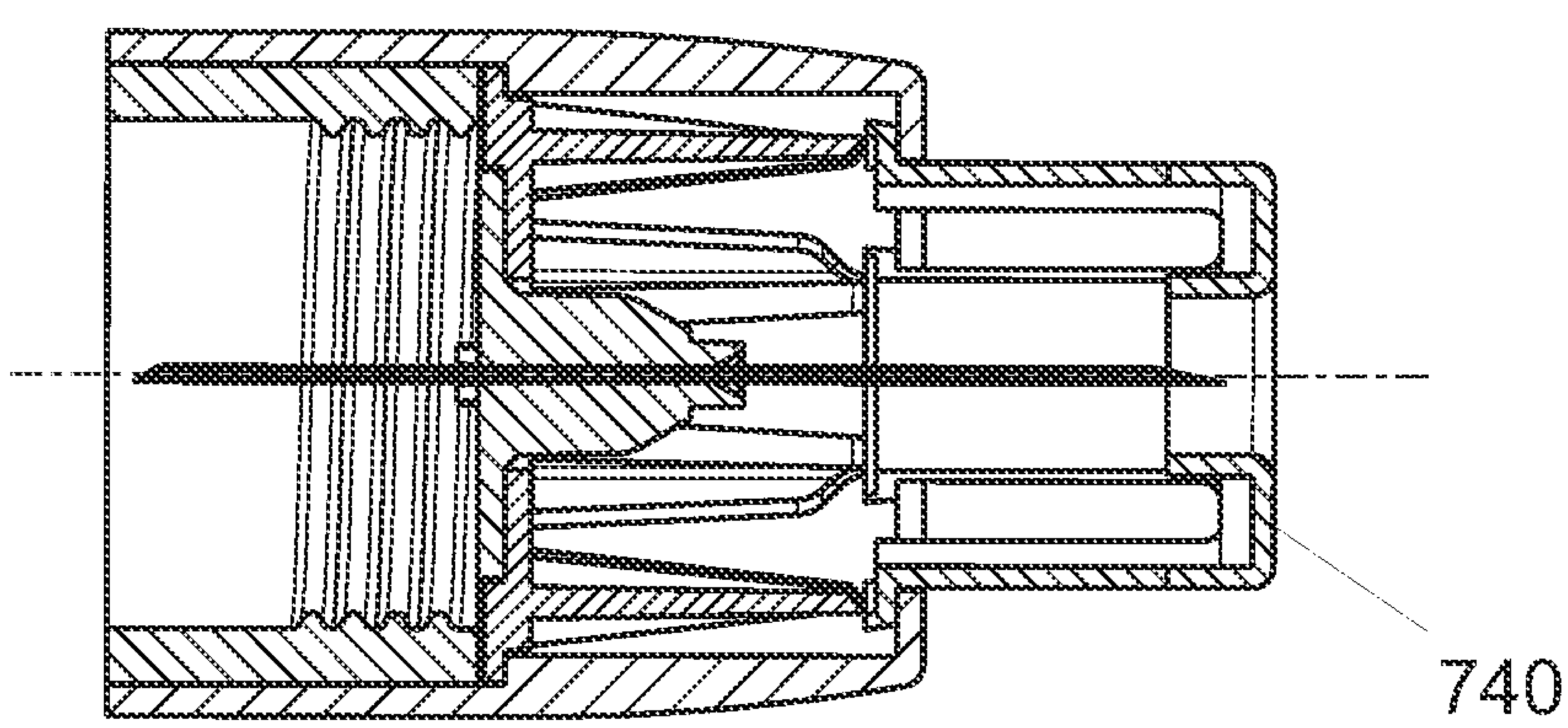

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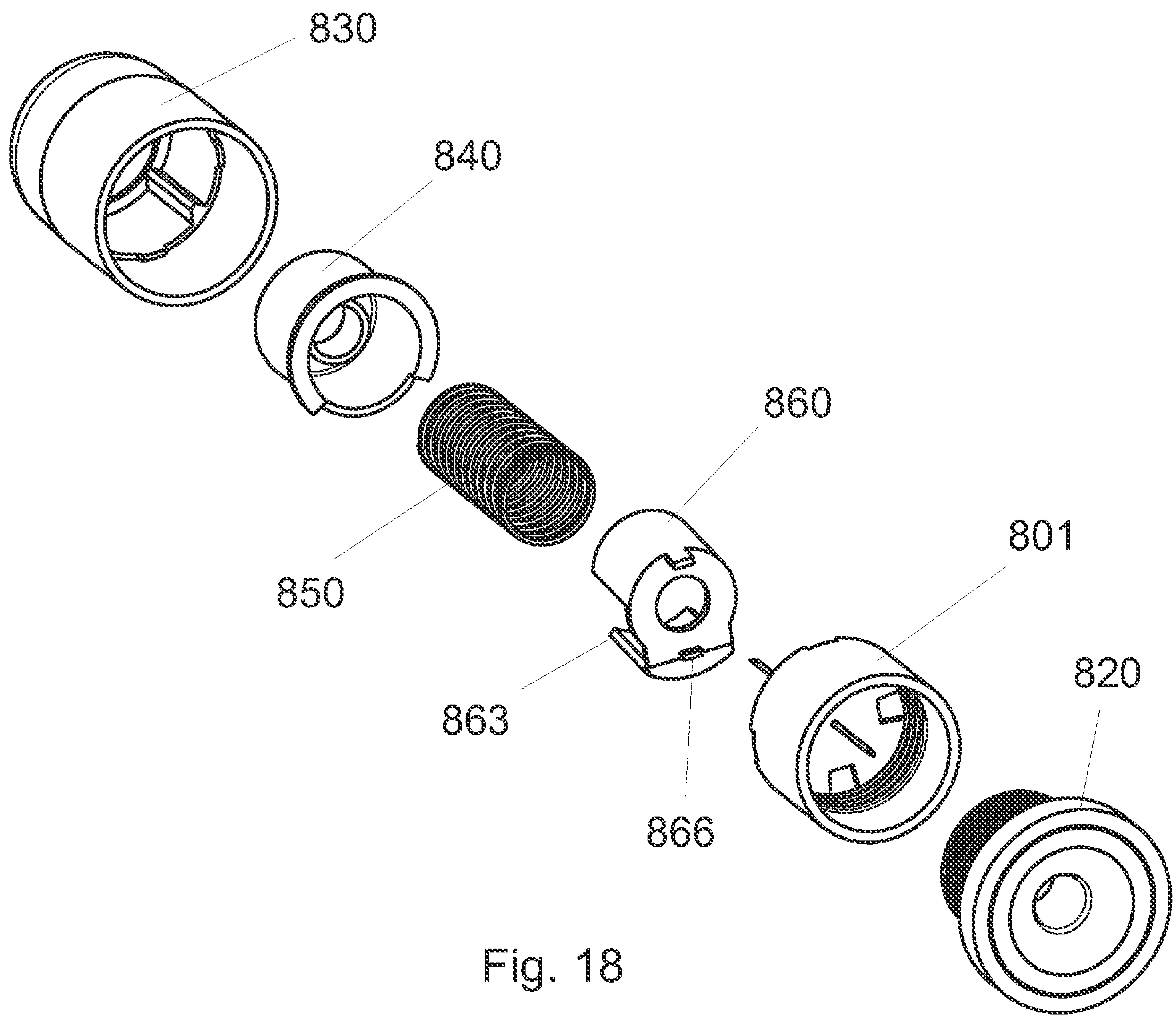

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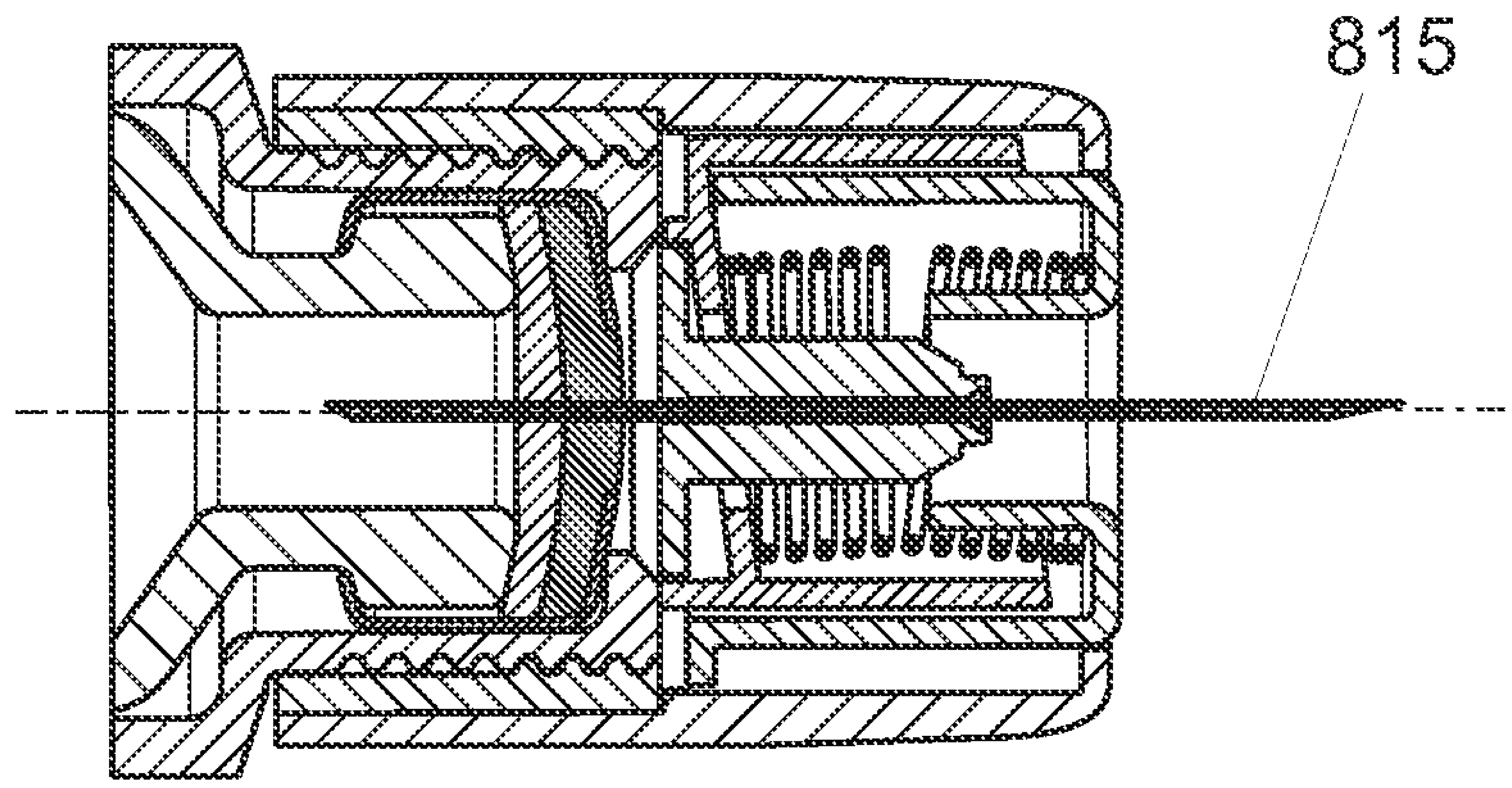

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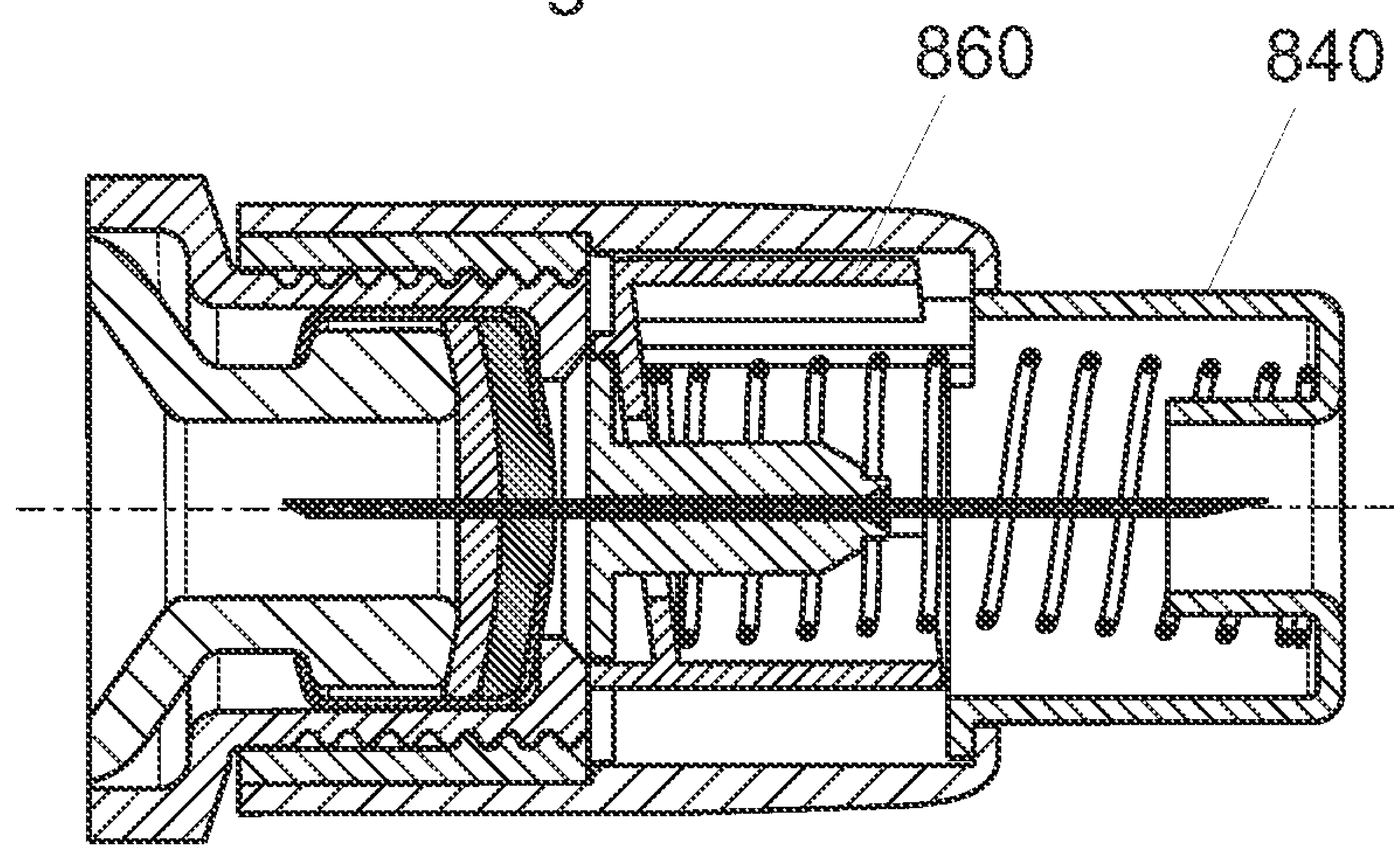

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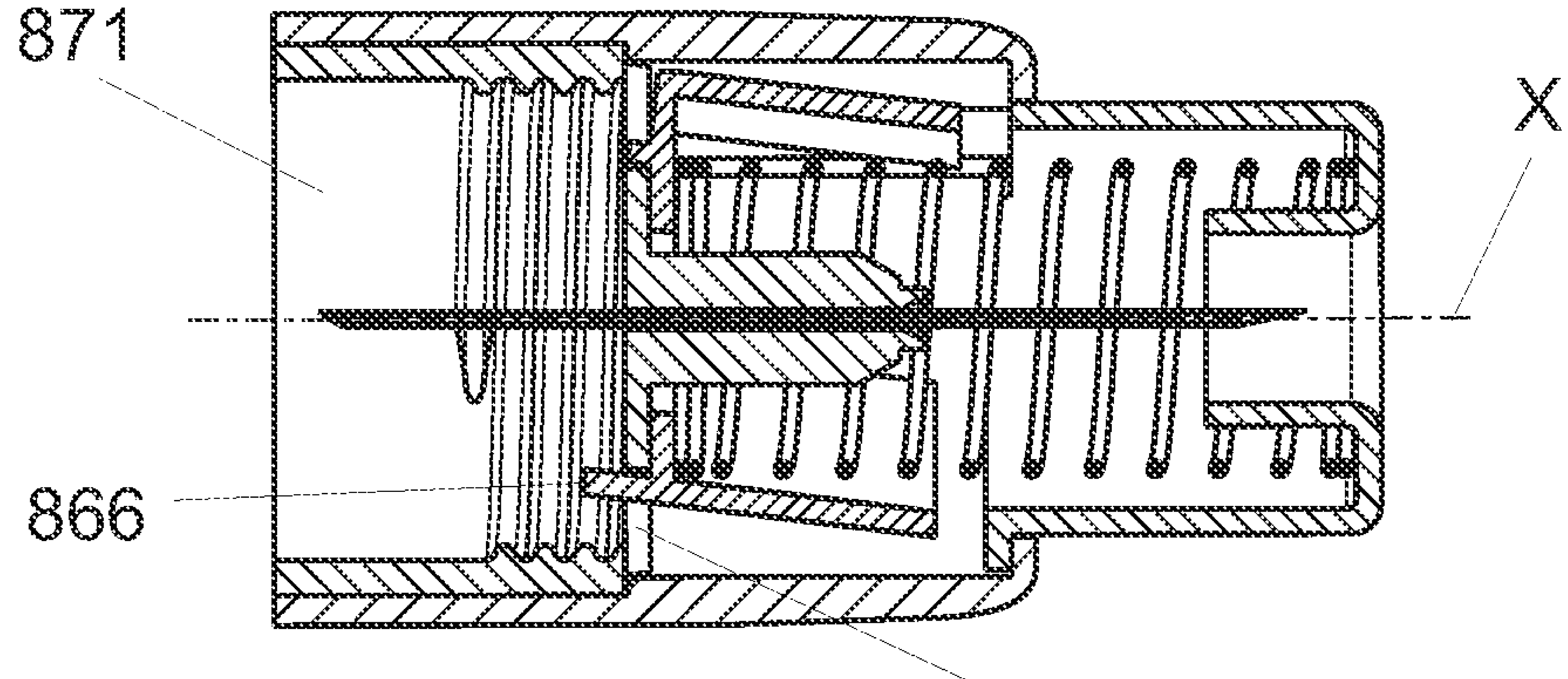

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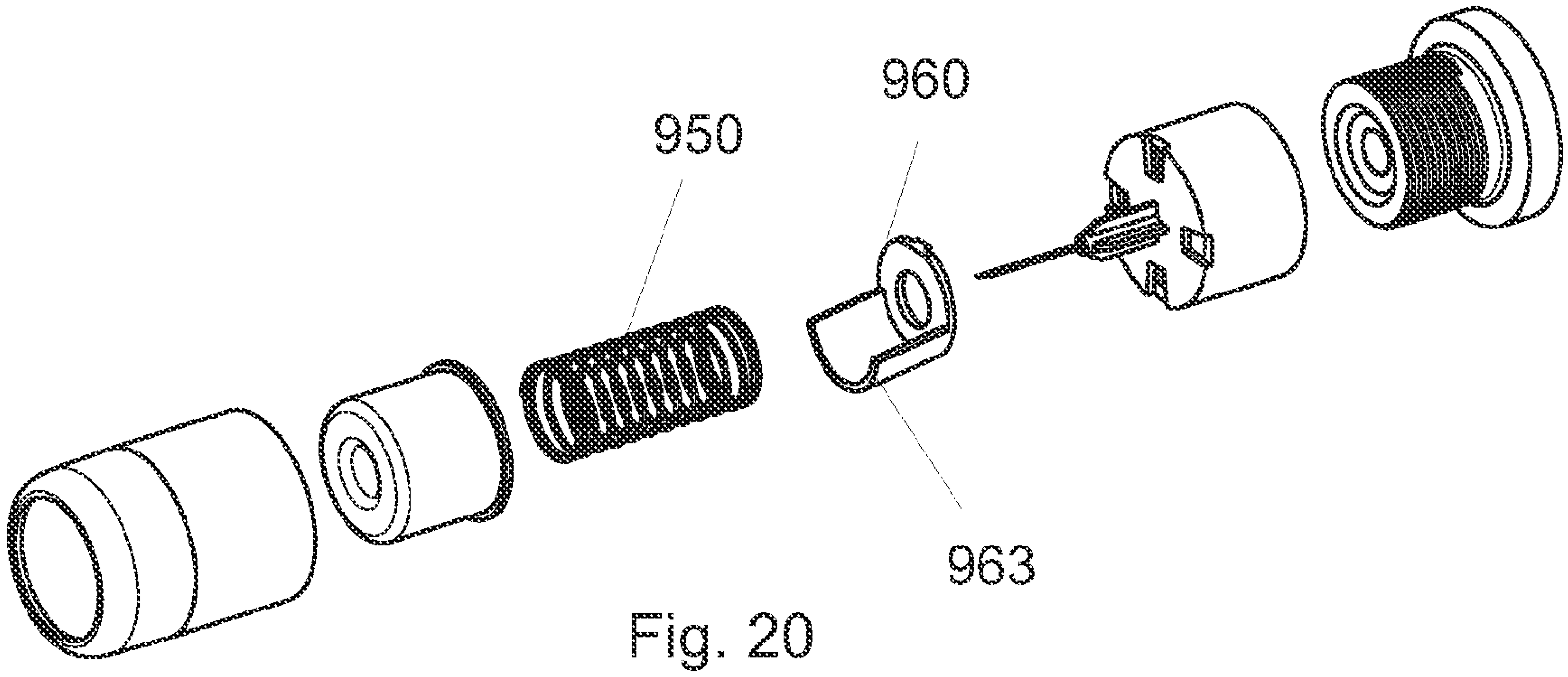

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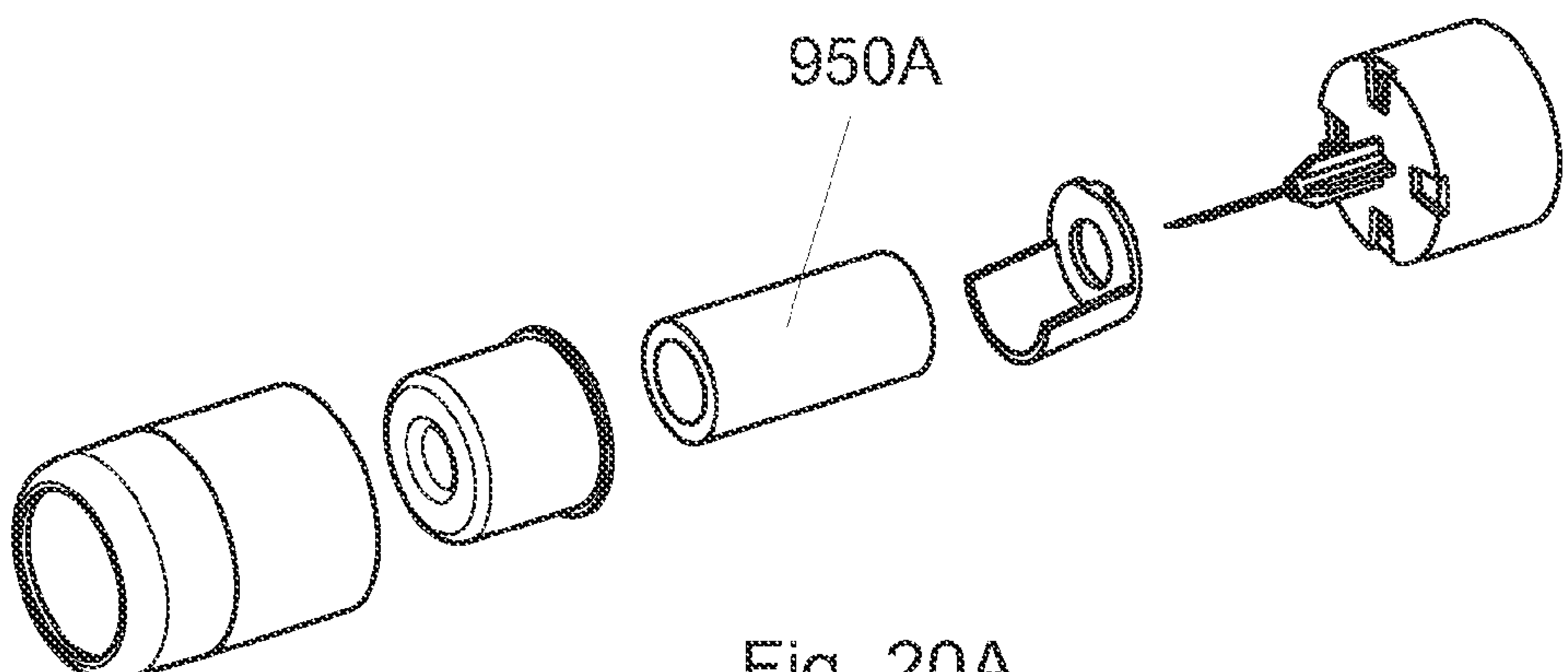

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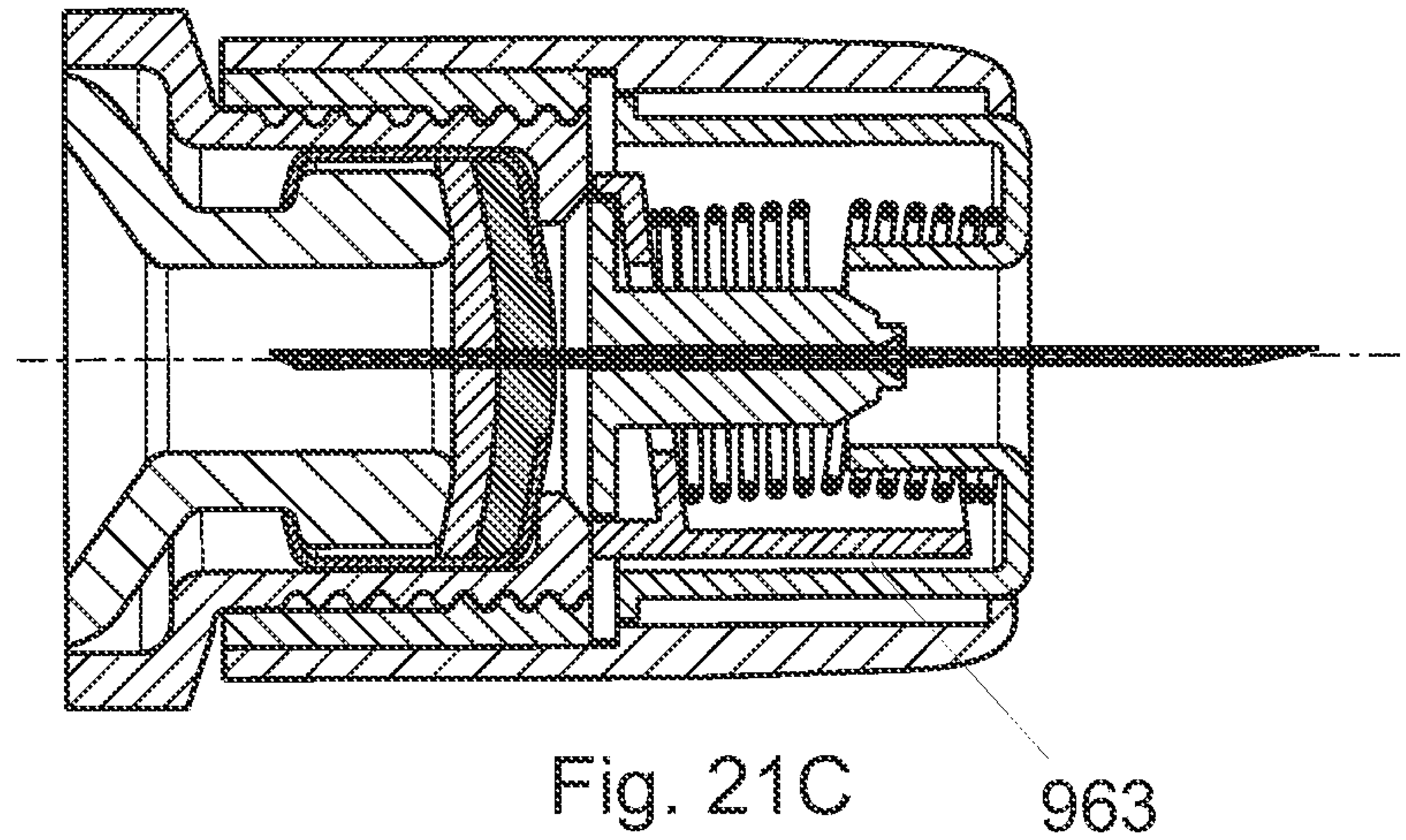

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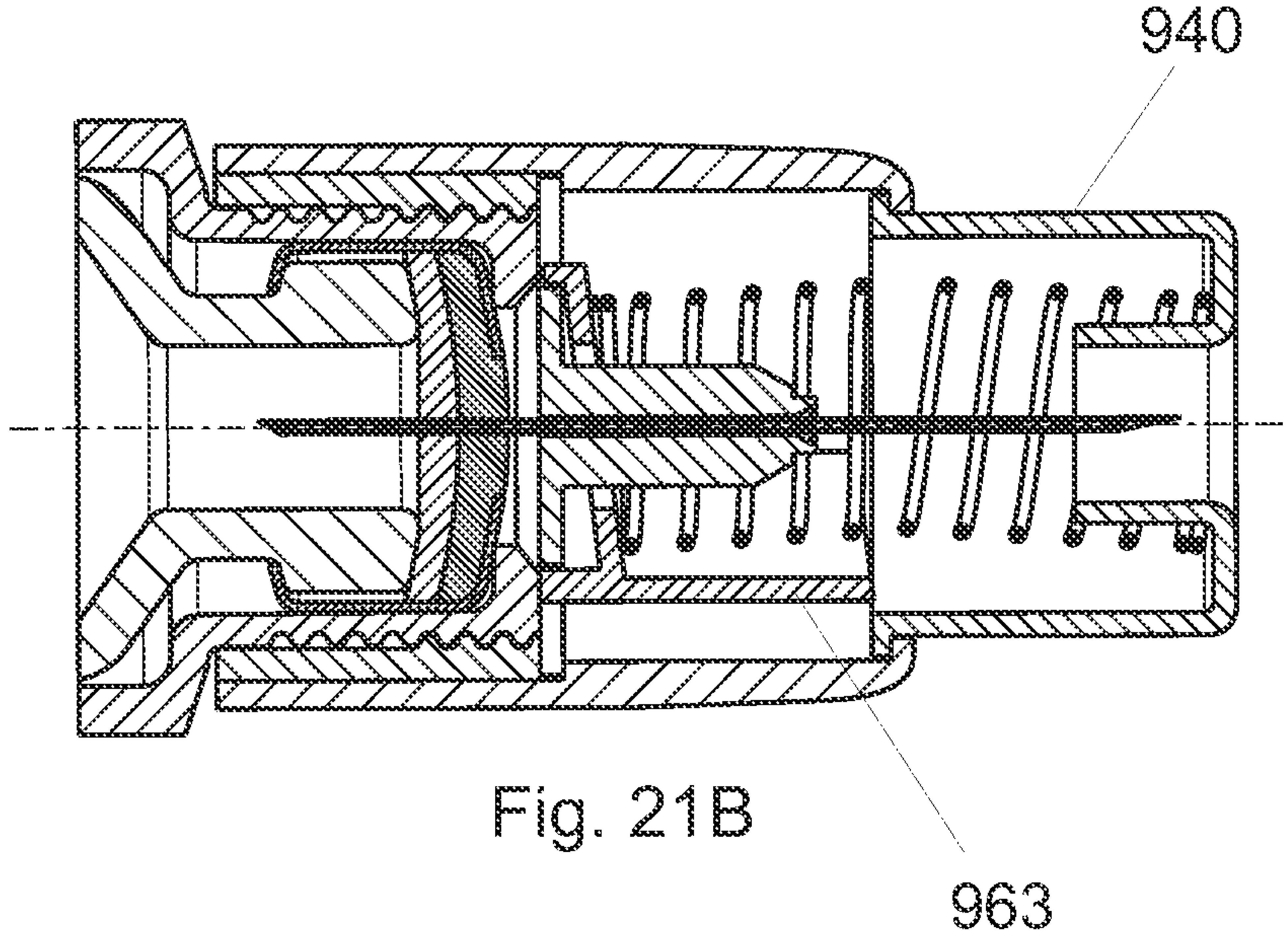

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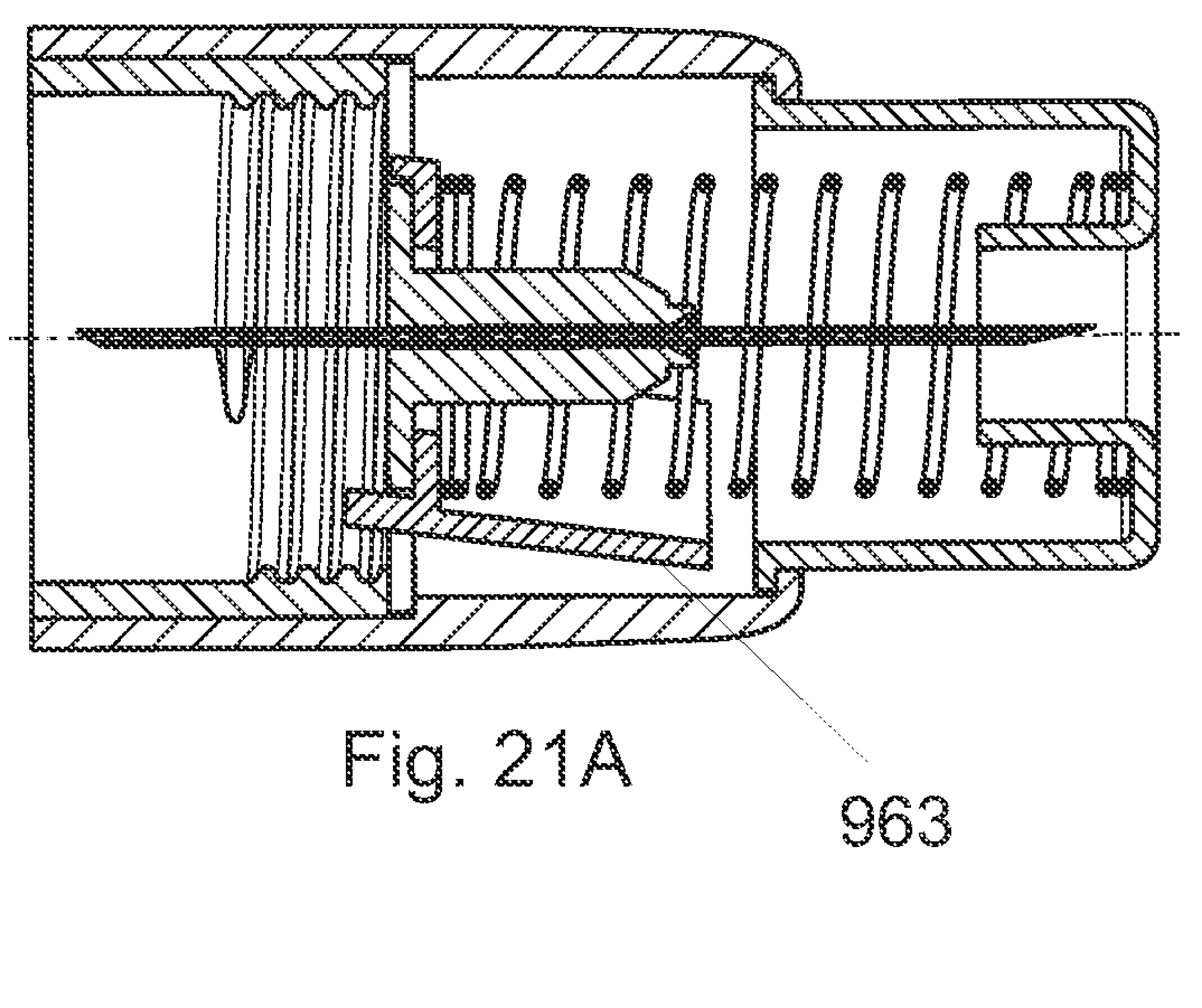

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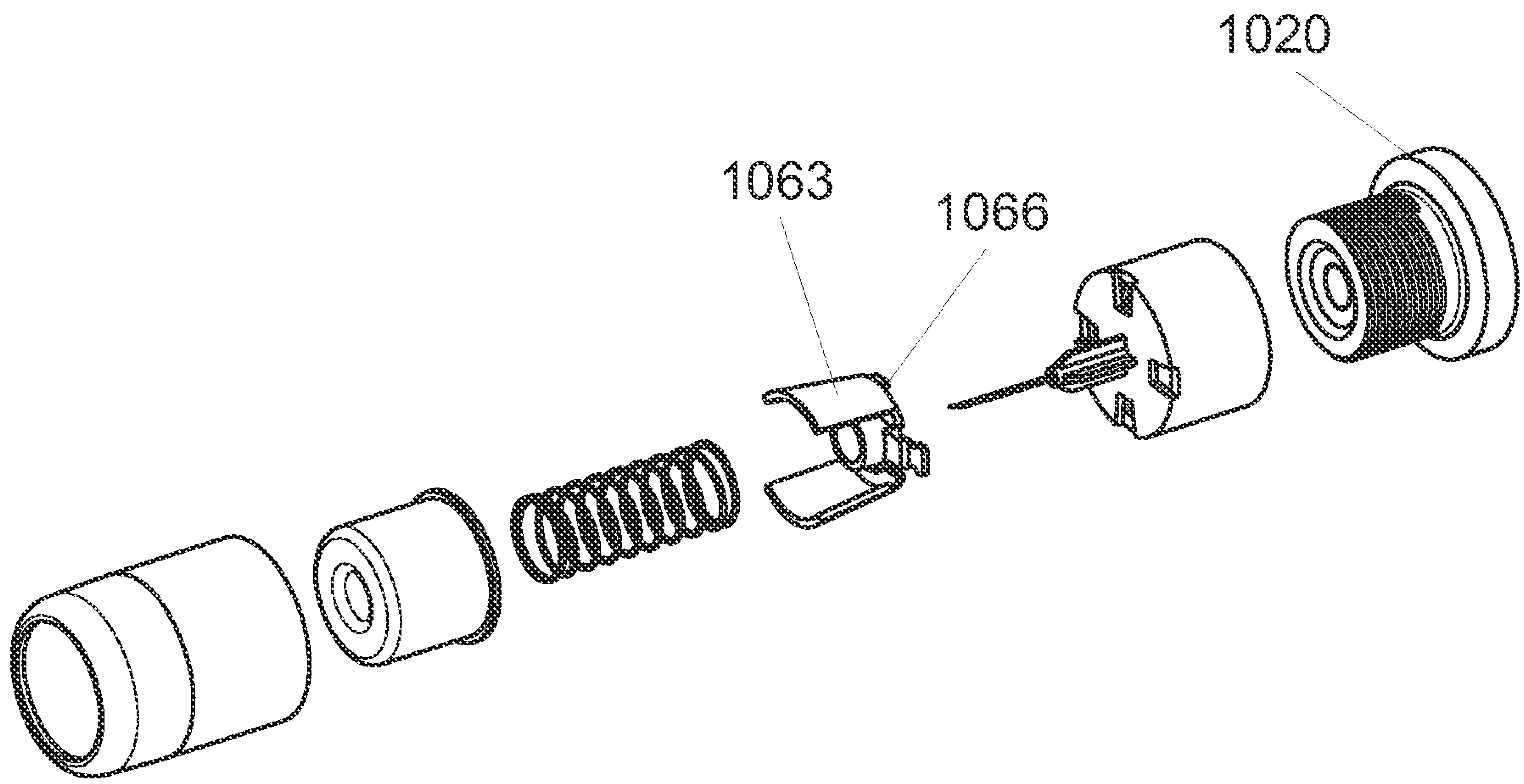

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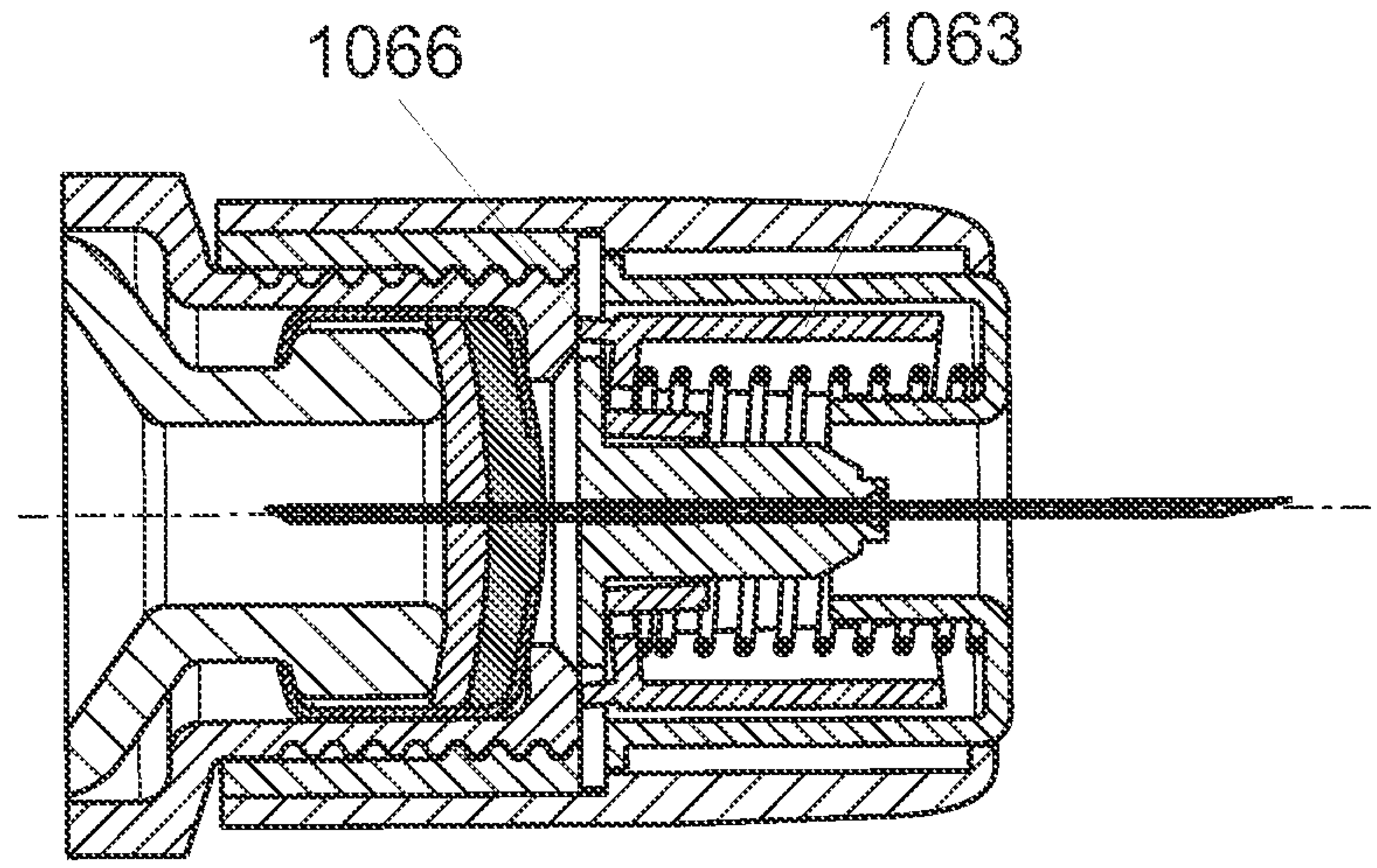

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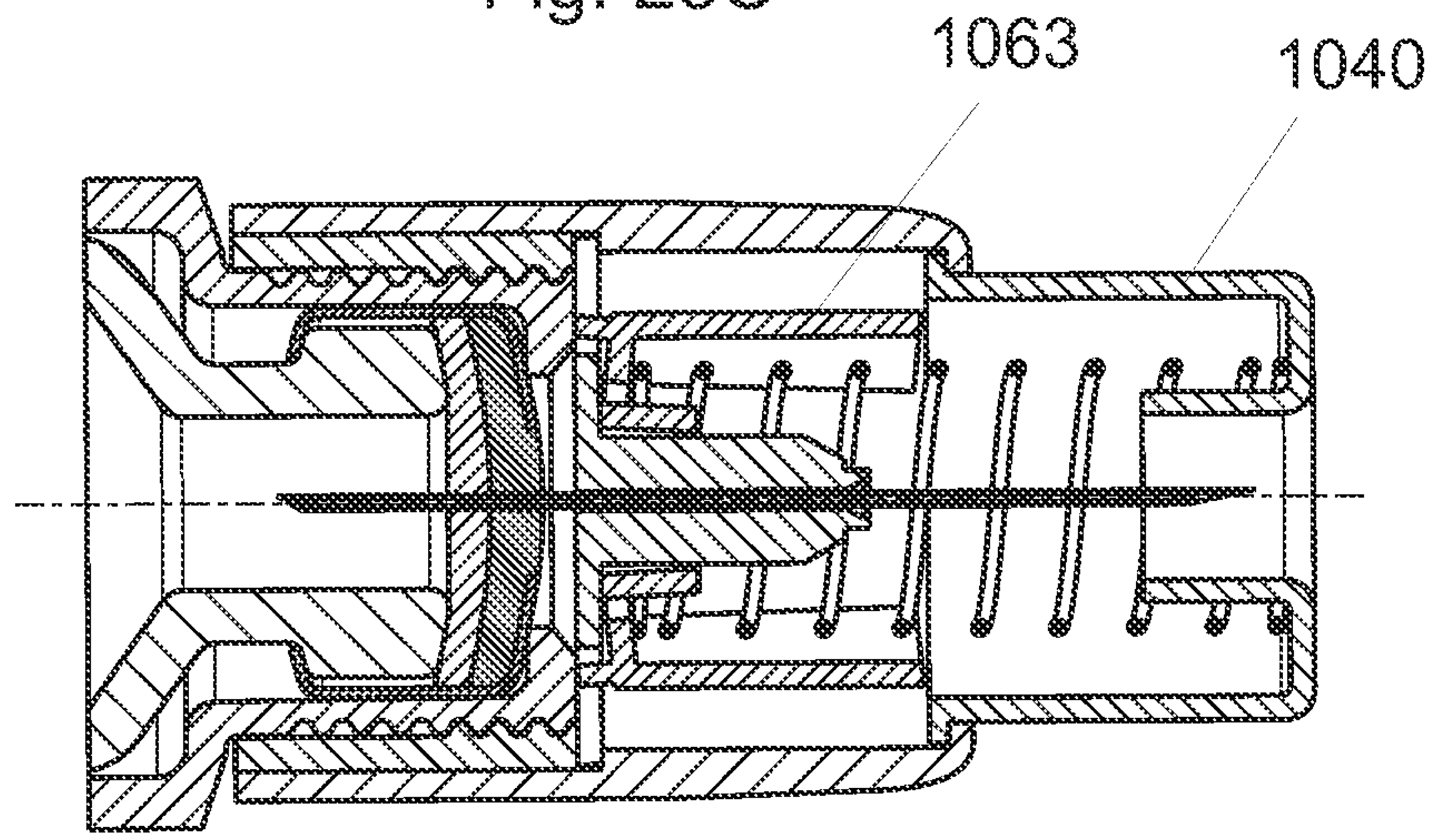

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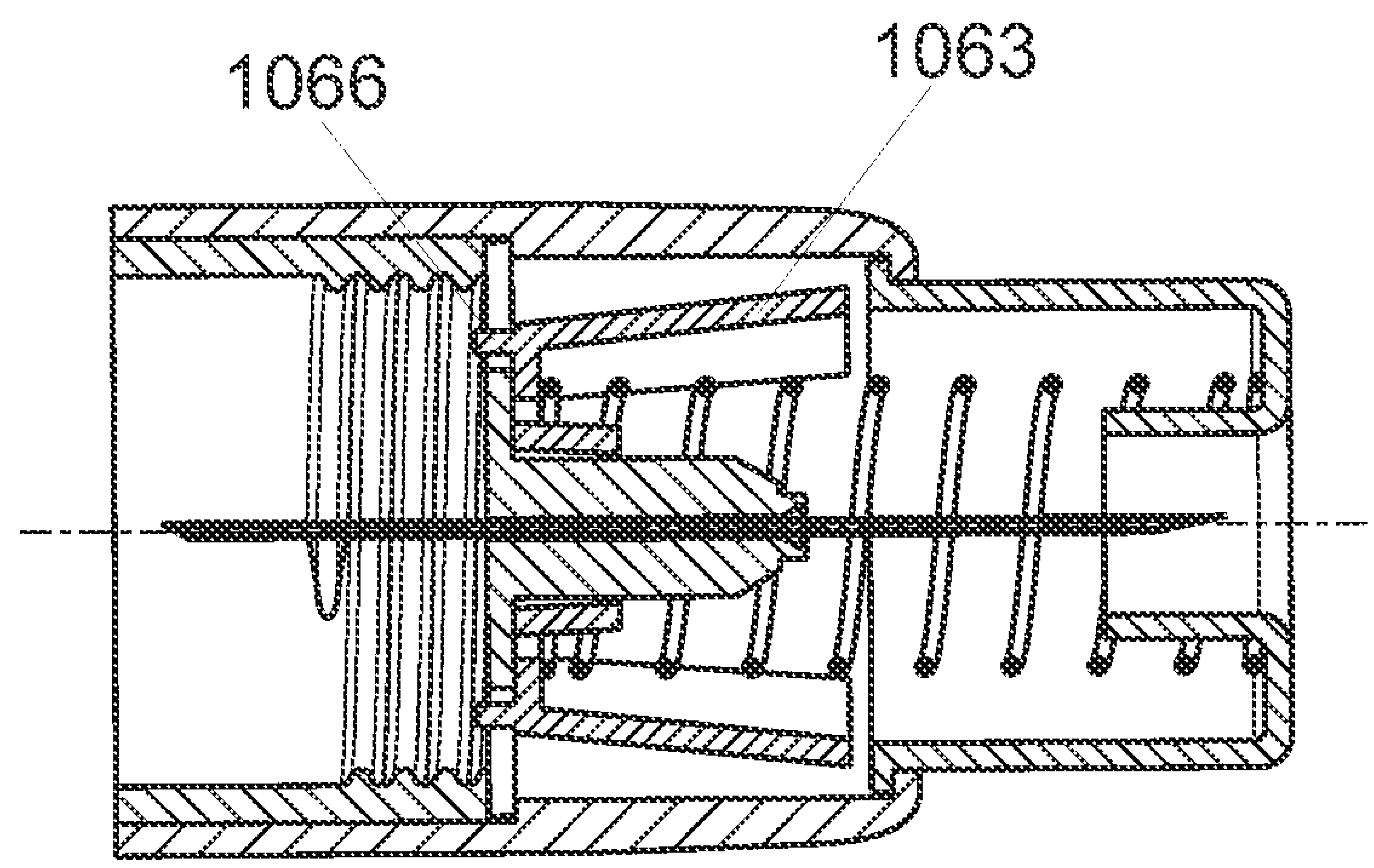

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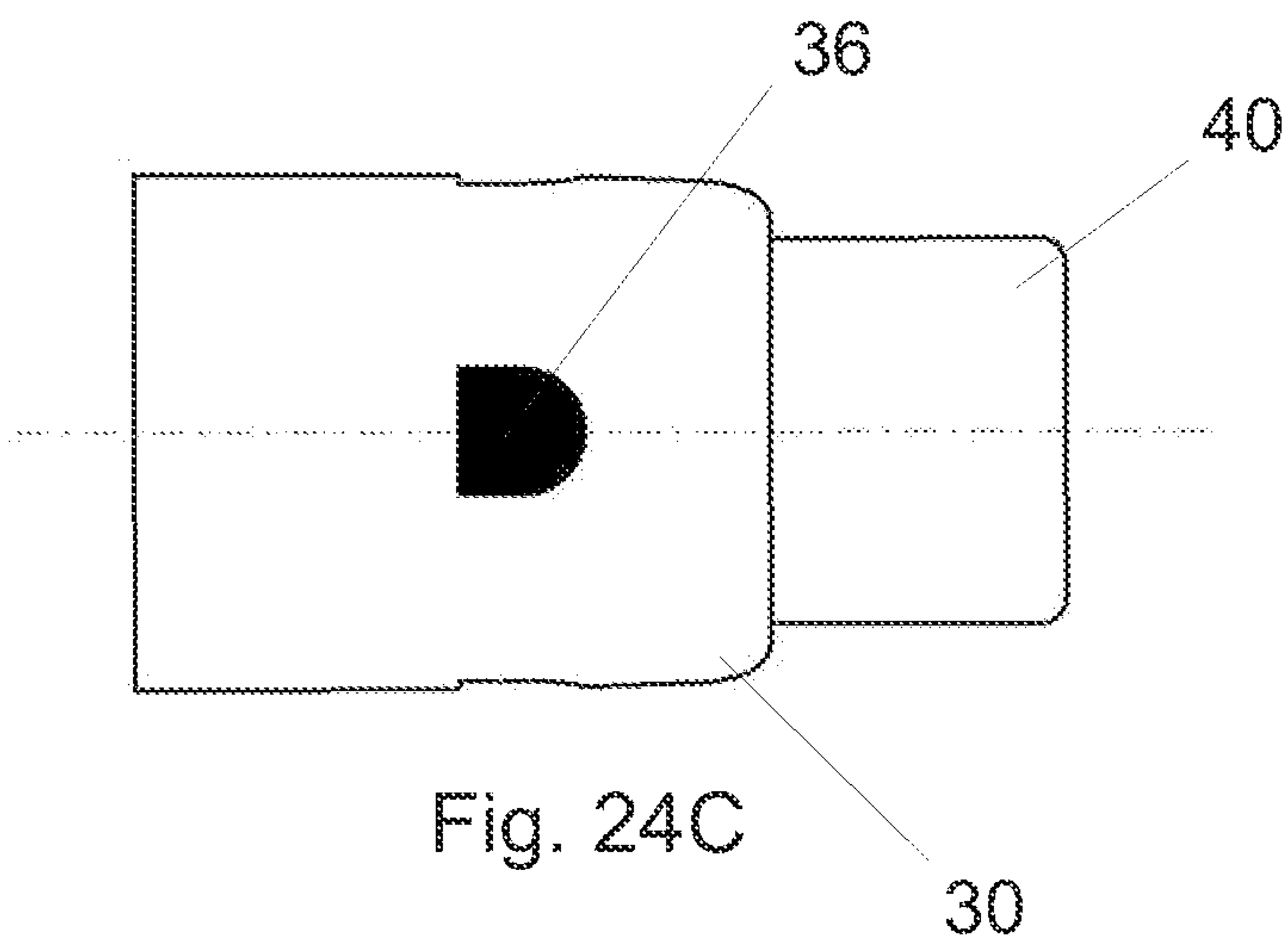

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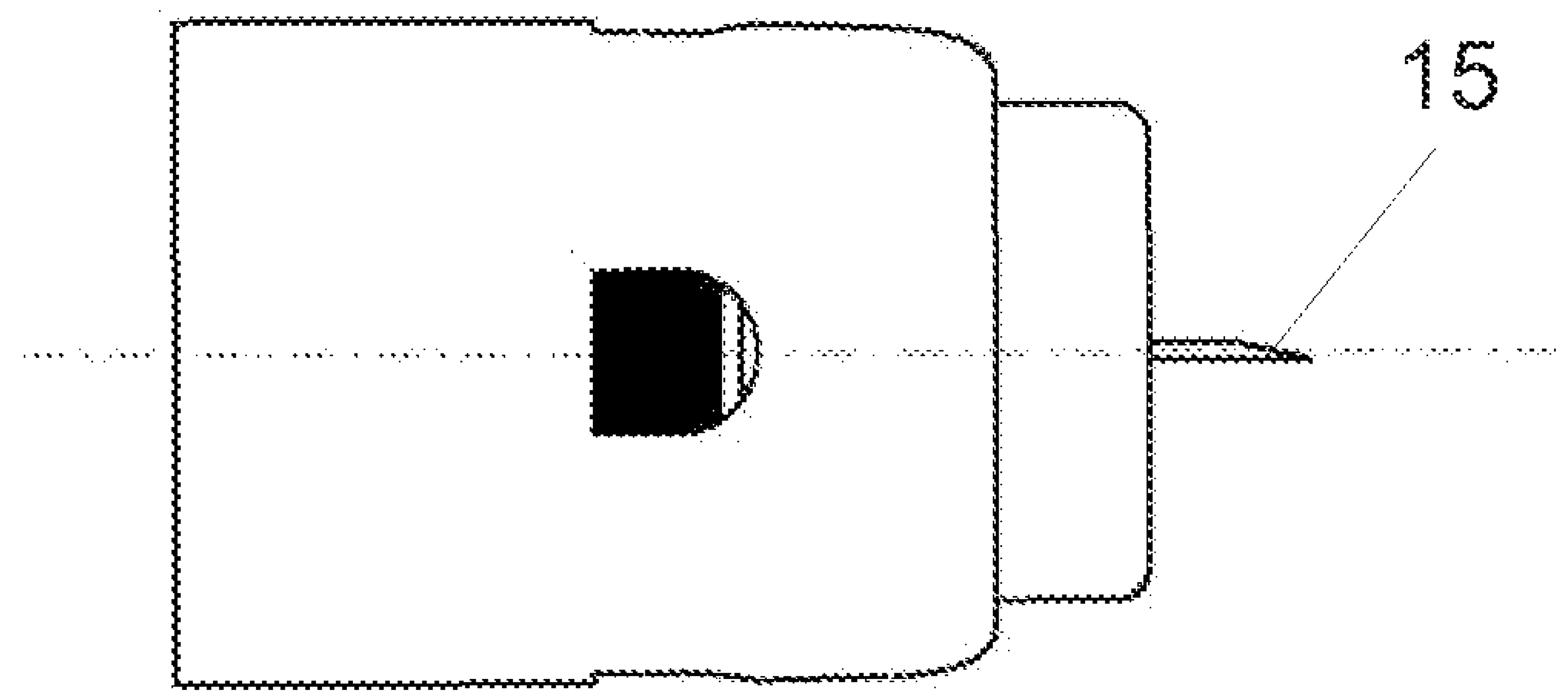

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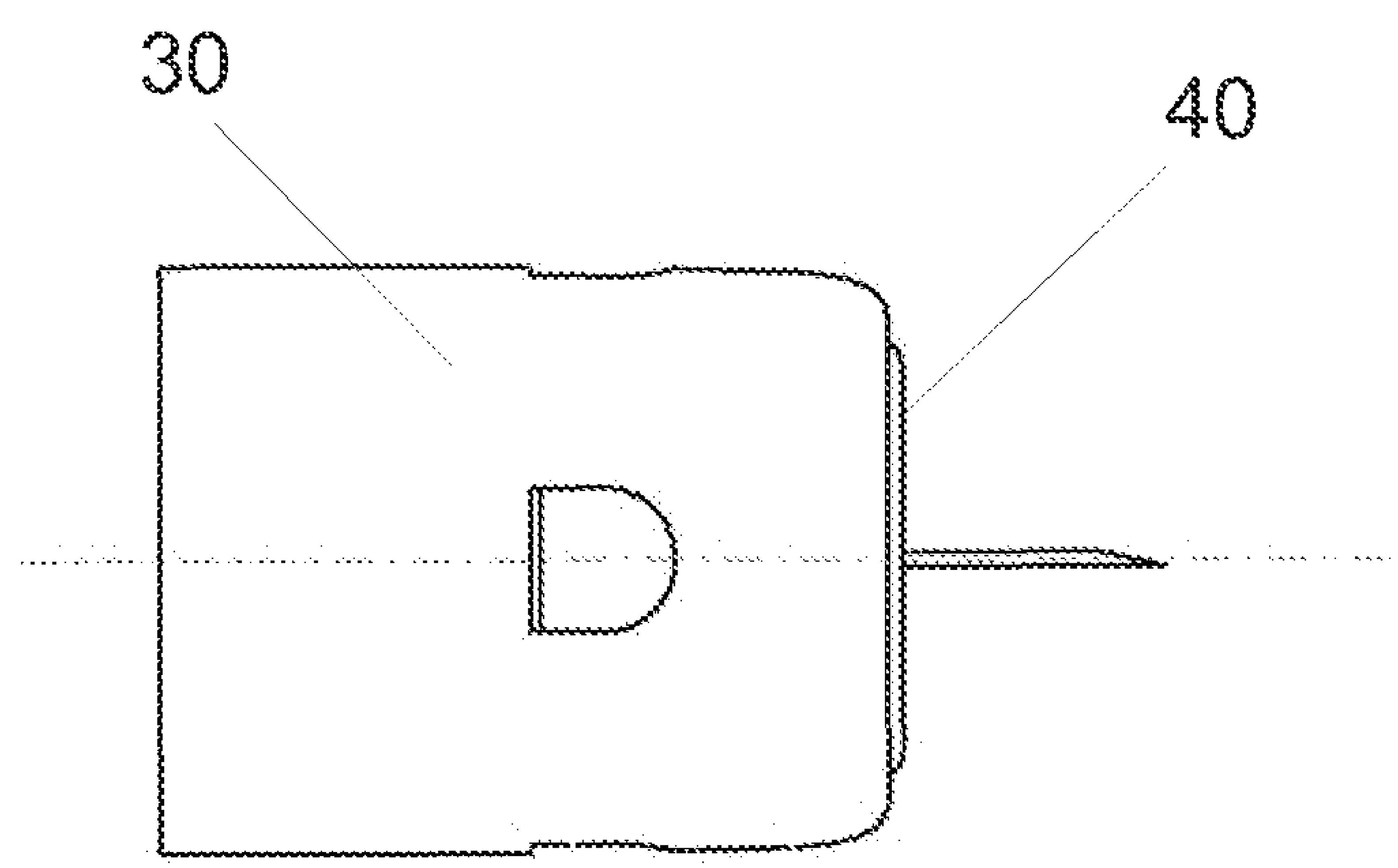

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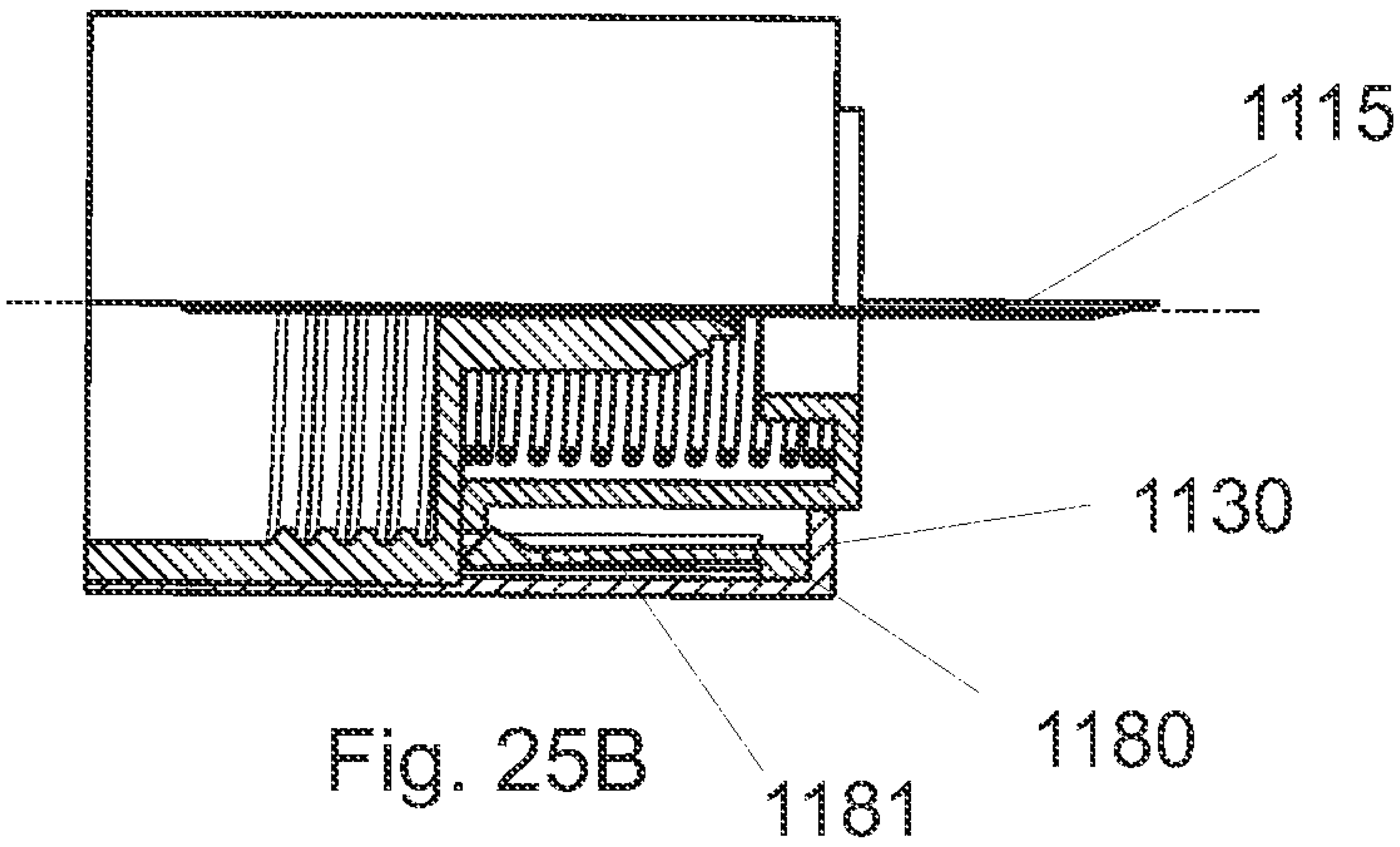

Fig. 25B

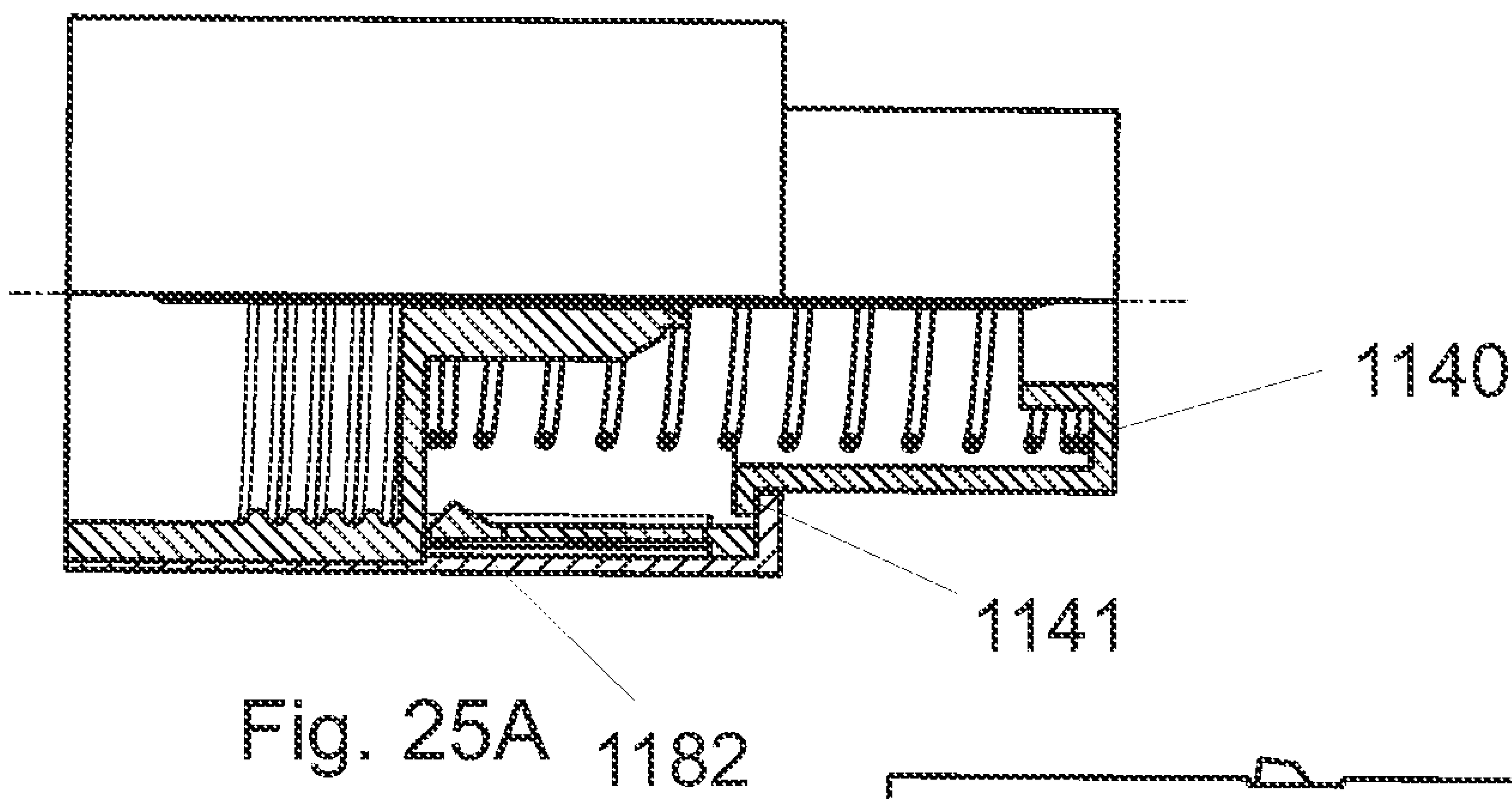

Fig. 25A

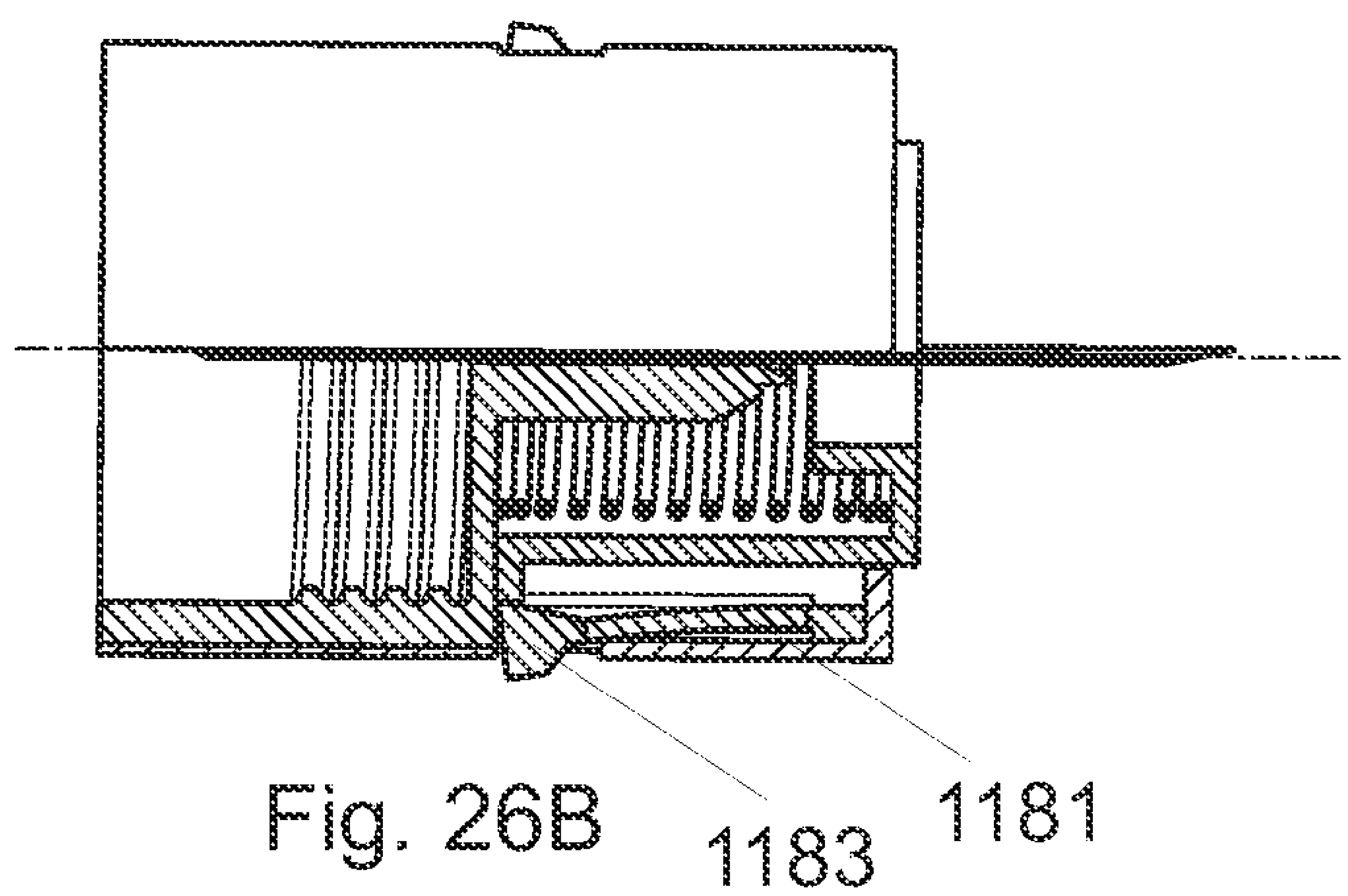

Fig. 26B

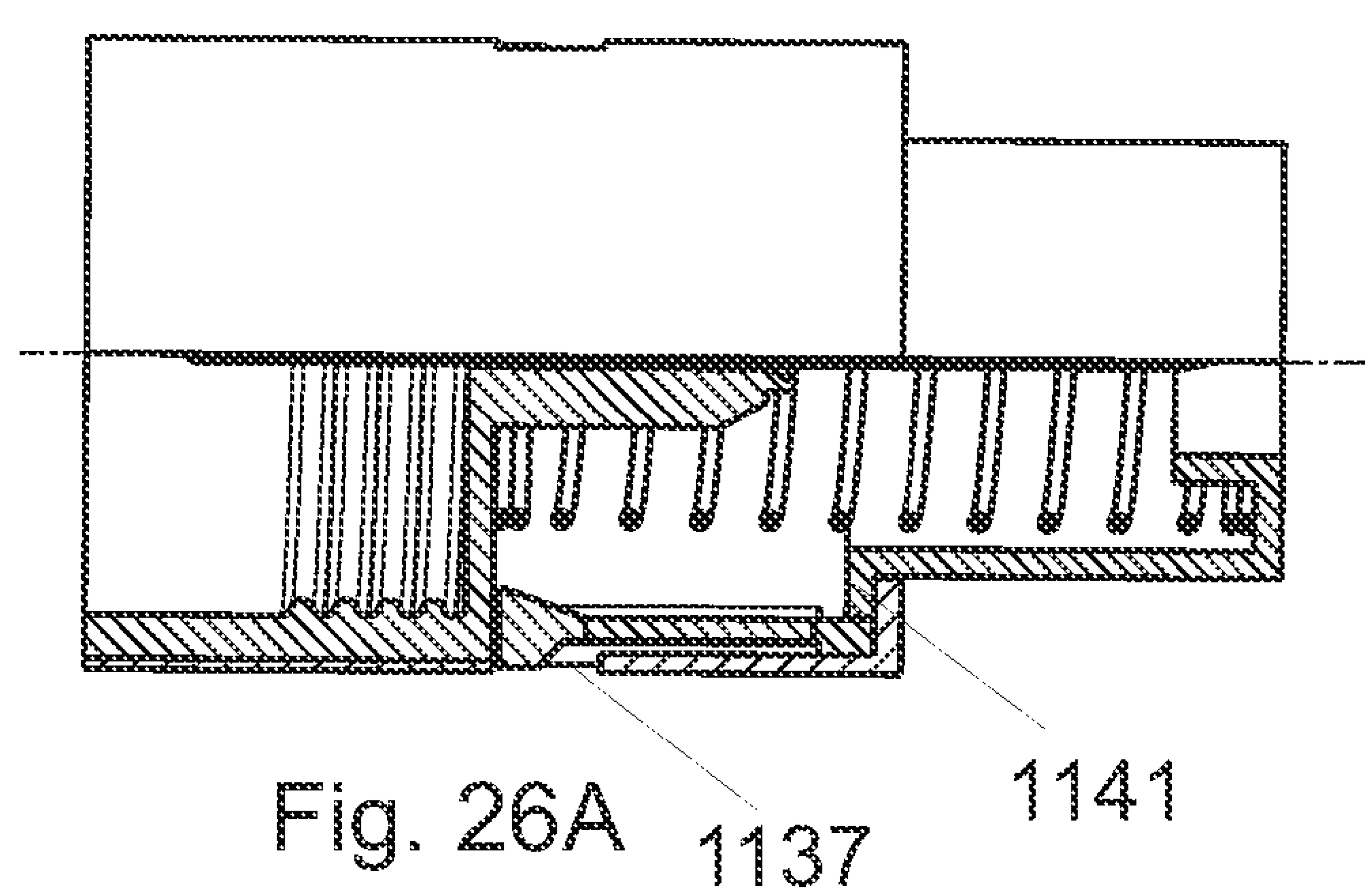

Fig. 26A

SHIELDABLE NEEDLE ASSEMBLY WITH BIASED SAFETY SHIELD

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a 35 U.S.C. §371 national stage application of International Patent Application PCT/EP2007/062759 (published as WO 2008/077706), filed Nov. 23, 2007, which claimed priority of European Patent Application 06126970.0, filed Dec. 22, 2006; this application further claims priority under 35 U.S.C. §119 of U.S. Provisional Application 60/878,574, filed Jan. 4, 2007.

THE TECHNICAL FIELD OF THE INVENTION

The invention relates to a needle assembly and especially to a needle having a shielded needle cannula.

DESCRIPTION OF RELATED ART

Needle assemblies are commonly used to either inject substances into or extract substances out of human or animal bodies. Such needle assemblies are typically disposable and are discarded after use. The problem presented by the disposal of a needle assembly, and indeed, by any handling of the needle assembly, is the potential risk of being injured by the sharp end of the needle cannula. This is particular dangerous when following after the penetration of a patients skin since the needle cannula then may be contaminated and therefore capable of spreading diseases such as hepatitis and HIV.

A great number of needle assemblies have been developed where the needle cannula is concealed by a spring loaded and telescopically movable shield during the injection. These needle assemblies can be divided into two different kinds of needles assemblies.

The first kind is often referred to as safety needles and has a spring loaded shield which covers the sharp end of the needle cannula both before injection, during injection and especially after injection. Such safety needle further has irreversible locking means locking the shield in the position covering the needle cannula after only one injection. Such safety needles are disclosed in e.g. WO 03/066141, EP 1.289.587 and in EP 1.448.256.

A second kind of shielded needle is disclosed in WO 99/25402 and in WO 01/76665. The shield disclosed is telescopically movable against the force of a spring located between the hub and the shield. This needle assembly has no irreversible lock and can therefore be used for multiple injections in the same way as a common non-shielded injection needle.

As it is apparent from WO 99/25402 such injection needle is ready for injection at any time, however the same kind of needle assembly which can be used for multiple injections can also be made in a way requiring the user to actively unlock the shield prior to each injection. Such needle assembly is disclosed in WO 01/76665. Here the locking element must be moved into a new axial track prior to each injection by applying an axial pressure on the shield.

Instead of attaching the shield to the hub as in the previous examples, WO05/035029 discloses an injection pen with a common non-shielded injection needle and an auxiliary shield-mechanism forming part of the injection pen.

It is henceforth a problem with injection needle assemblies that any person handling the needle is in a potential risk of being accidentally injured by the needle. For the second type

of needle assemblies that do not lock after injection there is also a danger for persons handling the needle assembly after it has been discarded.

Thus, there is a need for a needle assembly that can provide a higher degree of safety against accidental needle stick injuries in more situations.

DESCRIPTION OF THE INVENTION

It is an object of the present invention to provide a needle assembly having a shielded needle cannula which can be locked or unlocked dependent on the situation of use.

The shield is constantly urged in the distal direction by the biasing means such that the tip of the needle cannula is covered. When the needle assembly is in its unlocked position it is possible to telescope the shield in the proximal direction which is preferably done by pressing the shield against the skin of the user during injection. In the locked position, the shield is prevented from telescoping. The releasable locking means cooperates with the connecting means such that the locking means are only released upon activation of the connecting means. When the locking means cooperates with the connecting means to be released when the connecting means are activated it is possible for a user to use the injection device to unlock the shield such that when a user connects the needle assembly to the injection device the needle assembly is automatically unlocked whereas when it is removed from the injection device it is automatically locked again. As a result of this the needle assembly is always locked when dismounted and unlocked when mounted.

It is however also possible to make it such that the needle assembly can be manually shifted between a locked and an unlocked mode when mounted, whereas it is always locked when dismounted.

The connecting means which is usually a thread connection or a bayonet coupling is normally located at the proximal end of the hub ready to be connected to an injection device. The releasable locking means is usually provided with a number of activating parts or extensions which protrudes into the area of the connecting means such that the activating parts are activated when an object such as an injection device enters into the connecting area and interfaces the connecting means.

Further a separate locking element can be provided. The activating means are preferably provided on the locking element which is moved from the locking to the unlocking position by activation from the injection device. The movement of the locking element can either be rotational or axial or a combination thereof. Preferably, a thread connection secures that the locking element is rotated when it is axially moved, in this way the locking element can be moved to a new rotational position as it is axially moved e.g. by the injection device.

The needle assembly and injection pen together forms a system were it is assured that the safety shield can only be telescoped once the needle assembly is mounted on the injection device, further it is also assured that when the needle assembly is dismounted the shield covering the needle cannula is locked such that a user can not come into contact with the sharp end on the needle cannula.

In addition to this an overriding locking mechanism can be provided such that the safety shield can be shifted between a locked and an unlocked position only when the needle assembly is mounted on an injection device.

DEFINITIONS

An "injection pen" is typically an injection apparatus having an oblong or elongated shape somewhat like a pen for writing. Although such pens usually have a tubular cross-section, they could easily have a different cross-section such as triangular, rectangular or square or any variation around these geometries.

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs includes pharmaceuticals such as peptides, proteins (e.g. insulin, insulin analogues and C-peptide), and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form.

Correspondingly, the term "subcutaneous" injection is meant to encompass any method of transcutaneous delivery to a subject.

Further the term "injection needle" defines a piercing member adapted to penetrate the skin of a subject for the purpose of delivering or removing a liquid.

The term "Needle Cannula" is used to describe the actual conduit performing the penetration of the skin during injection. A needle cannula is usually made from a metallic material and connected to a hub to form an injection needle. A needle cannula could however also be made from a polymeric material or a glass material. The hub which carries the connecting means for connecting the injection needle to an injection apparatus is usually moulded from a suitable thermoplastic material.

"Cartridge" is the term used to describe the container containing the insulin. Cartridges are usually made from glass but could also moulded from any suitable polymer. A cartridge or ampoule is preferably sealed at one end by a pierceable membrane which can be pierced e.g. by an injection needle. The opposite end is closed by a plunger or piston made from rubber or a suitable polymer. The plunger or piston can be slidable moved inside the cartridge. The space between the pierceable membrane and the movable plunger holds the insulin which is pressed out as the plunger decreased the volume of the space holding the insulin.

All references, including publications, patent applications, and patents, cited herein are incorporated by reference in their entirety and to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

All headings and sub-headings are used herein for convenience only and should not be constructed as limiting the invention in any way.

The use of any and all examples, or exemplary language (e.g. such as) provided herein, is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be constructed as indicating any non-claimed element as essential to the practice of the invention. The citation and incorporation of patent documents herein is done for convenience only and does not reflect any view of the validity, patentability, and/or enforceability of such patent documents.

This invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be explained more fully below in connection with a preferred embodiment and with reference to the drawings in which:

FIG. **1** Show an exploded view of an example of a hidden needle assembly.

FIG. **2** A-B Show a cross section of the hidden needle assembly of FIG. **1**.

FIG. **3** Show an exploded view of an example of a hidden needle assembly.

FIG. **4** A-C Show a cross section of the hidden needle assembly of FIG. **3**.

FIG. **5** Show an exploded view of an example of a hidden needle assembly.

FIG. **6** A-B Show a cross section of the hidden needle assembly of FIG. **5**.

FIG. **7** Show an exploded view of an example of a hidden needle assembly

FIG. **8** A-C Show a cross section of the hidden needle assembly of FIG. **6**.

FIG. **9** Show an exploded view of an example of a hidden needle assembly.

FIG. **10** A-B Show a cross section of the hidden needle assembly of FIG. **9**.

FIG. **11** Show an exploded view of an example of a hidden needle assembly.

FIG. **12** Show an exploded view of the hidden needle assembly of FIG. **11**.

FIG. **13** A-C Show a cross section of the hidden needle assembly of FIGS. **11** and **12**.

FIG. **14** Show an exploded view of an example of a hidden needle assembly.

FIG. **15** A-C Show a cross section of the hidden needle assembly of FIG. **14**.

FIG. **16** Show an exploded view of an example of a hidden needle assembly.

FIG. **17** A-C Show a cross section of the hidden needle assembly of FIG. **16**.

FIG. **18** Show an exploded view of an example of a hidden needle assembly.

FIG. **19** A-C Show a cross section of the hidden needle assembly of FIG. **18**.

FIG. **20** A-B Show an exploded view of an example of a hidden needle assembly.

FIG. **21** A-C Show a cross section of the hidden needle assembly of FIG. **20**A.

FIG. **22** Show an exploded view of an example of a hidden needle assembly.

FIG. **23** A-C Show a cross section of the hidden needle assembly of FIG. **22**.

FIG. **24** Show a side view of an example of a hidden needle assembly.

FIG. **25** A-B Show a view of a hidden needle assembly.

FIG. **26** A-B Show a view of a hidden needle assembly.

The figures are schematic and simplified for clarity, and they just show details, which are essential to the understanding of the invention, while other details are left out. Throughout, the same reference numerals are used for identical or corresponding parts.

DETAILED DESCRIPTION OF EMBODIMENT

When in the following terms as "upper" and "lower", "right" and "left", "horizontal" and "vertical", "clockwise" and "counter clockwise" or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

In that context it may be convenient to define that the term "distal end" in the appended figures is meant to refer to the end of the needle cannula penetrating the patient whereas the term "proximal end" is meant to refer to the opposite end pointing away from the patient in a situation of use.

Example 1

FIG. **1-2**

FIGS. **1** and **2** discloses a hub **1** carrying a needle cannula **15**. In use the needle cannula **15** forms a conduit between the interior of a cartridge **25** secured in an injection device **20** and the subcutaneous layer of a user. The hub **1** is surrounded by an outer shield **30** which is permanently connected to the hub **1** e.g. by snapping, gluing or welding the two parts **1**, **30** together, alternatively the two parts **1**, **30** can be formed as one part during moulding.

The hub **1** is further provided with interior coupling means **2** such as a thread or one or more protrusions for a bayonet coupling as described in EP 1,536,854. These engagement means **2** co-operates with similar engaging means **21** on the distal end of the injection device **20** in order to secure the hub **1** to the injection device **20**.

Although the term "injection device" is used through out this application, a Penfill® equipped with an adapter top to fit into a Novo Nordisk pen system according to U.S. Pat. No. 5,693,027 or similar containers with drugs provided with connecting means for a needle assembly is also considered to fall under this term.

The needle cannula **15** has a distal end **16** with a sharp point for penetrating the skin of the user and a proximal end **17** for penetrating into the cartridge **25** holding the drug to be injected.

The outer shield **30** is provided with a rim **31** bordering an opening **32** at the distal end. A safety shield **40** which preferably is provided with a rib **41** is prevented from falling out the opening **32** due to the engagement between the rim **31** and the rib **41**.

A resilient element **50** such as a spring is located between the safety shield **40** and the hub **1**, urging the safety shield **40** in the distal direction whereby the safety shield **40** covers the distal end of the needle cannula **10**.

The hub **1** is on its distal side provided with a number of arms **3** extending in the distal direction. These arms **3** are secured to the remaining part of the hub **1** by film hinges **4** such that the arms **3** can move flexible in a radial direction. The arms **3** could also be provided on a separate element which could be attached to the hub **1** e.g. by snapping, gluing or welding. The most distal end of these arms **3** is preferably provided with a shoulder **5**. The proximal side of the film hinges **4** is further provided with a proximally pointing protrusion **6** located radically displaced to the axial axis of the arms **3**.

In the initial position shown in FIG. 2A, the safety shield **40** is pressed forward by the spring **50** and the shoulder **5** on the arms **3** is positioned directly beneath the shield **40**. Due to the abutment between the shoulders **5** and the safety shield **40** it is not possible to telescope the safety shield **40** in the proximal direction.

When the injection device **20** is inserted into the hub **1** and secured in position as shown in FIG. 2B, the distal end of the injection device **20** abuts the protrusions **6**. This distally working pressure on the protrusions **6** makes the flexible film hinge **4** flex whereby the arms **3** and its shoulders **5** are moved inwardly toward the centre of the needle assembly due to the dislocated position of the protrusions **6**. This radial movement of the arms **3** and its shoulders **5** removes the shoulders **5** from its abutment with the safety shield **40**, which is hereafter movable in its axial direction.

When the injection has been finalized and the needle hub **1** is removed from the injection device **20**, the pressure is released from the protrusions **6**. This will make the flexible film hinge **4** flex back to its initial position where the arms **3** once again will be situated right beneath the safety shield **40** preventing axial movement of the safety shield **40**. Due to this mechanism, the safety shield **40** is only axially movable when connected to the injection device **20**.

Example 2

FIG. **3-4**

In a different example disclosed in FIGS. **3** and **4** the hub **101** carrying the needle cannula **115** is connected with the outer shield or alternatively moulded as one piece. A spring **150** is located between the hub **101** and the safety shield **140** urging the safety shield **140** in the distal direction. The inside surface of the safety shield **140** is provided with a number of raised ribs **142** which extends in the longitudinal direction. These ribs **142** can be formed in a multitude of different ways e.g. as protrusions.

Similar ribs or protrusions **162** are formed on the exterior surface of a locking element **160**. The locking element **160** is located inside the hub **101** and abuts the hub **101** proximally. Also proximally, the locking element **160** is provided with a number of fingers **166** which extends into the connecting area **171** of the hub **101**.

The hub **101** is divided into two areas by a partition **107**. The first area being the safety shield guiding area **172** and the second area being the connecting area **171** which is provided with means **102** for coupling the hub **101** to an injection device **120**. The injection device **120** and the hub **101** could also be provided with combined thread **122** and bayonet **123** coupling as described in EP 1.536.854. As could a broad variety of different ways of mounting the needle assembly on the injection device **120** be foreseen e.g. different snap or click-on mechanisms.

In this embodiment the injection device **120** is preferably provided with a number of distally located knobs **124**. These knobs **124** interact with the fingers **166** of the locking element **160**. When the hub **101** is connected to the injection device **120**, the injection device **120** and the hub **101** is usually rotated relatively to each other, the extend of the rotation depends of the type of connection. A threaded connection demands several full rotations where a bayonet coupling usually demands less than one full rotation. The situation just before the knobs **124** on the injection device **120** encounters the fingers **166** on the locking element is disclosed in FIG. 4B. At the end of the rotational movement between the hub **101** and the injection device **120** as depictured in FIG. 4C, the knobs **124** engages the fingers **166** of the locking element **160** forcing the locking element **160** to rotate. In order for the knobs **124** to abut properly to the fingers **166** a bayonet coupling or a steep thread is preferred.

The longitudinal ribs or protrusions **142** of the safety shield **140** are in the initial position located aligned with the similar ribs or protrusions **162** on the locking element **160**. In this way the safety shield **140** is prevented from axial movement. When the locking element **160** is rotated the ribs or protrusion **142**, **162** disengages and makes it possible to move the safety shield **140** in a telescopic movement as disclosed in FIG. 4C.

Once the user releases the hub **101** from the injection device **120** by rotating in the opposite direction, the position of the knobs **124** on the injection device **120** and the fingers **166** on the locking element **160** is designed such that the fingers **166** and thereby the locking element **160** is returned to the initial and locked position. The injection device **120** could e.g. be equipped with four knobs **124** as disclosed. When mounting the needle assembly to the injection device, the forefront of the knops **124** in the rotational direction abuts the fingers **166**, whereas when the needle assembly is dismounted the backfront of the next knob **124** abuts the finger **166** at its opposite end.

In order to prevent unintentional rotational movement between the locking element **160** and the hub **101** e.g. during transportion, a reversible click-arm **165** could be guided in a not shown track inside the hub **101**. This could also serve the purpose of providing the user with a sound signal.

Example 3

FIG. **5-6**

A similar embodiment is disclosed in FIGS. **5** and **6**. The hub **201** is provided with an internal thread **202** for connecting the hub **201** carrying the needle cannula **215** to an injection device **220**. An outer shield **230** is attached to the hub **201** or alternatively moulded in one piece with the hub **201**. The hub **201** is further provided with a centrally located tower **209** inside which the needle cannula **215** is glued to the hub **201**. This tower **209** is provided with an external thread **210**. A locking element **260** having an internal thread **261** surrounds the tower **209** and is threadedly engaged with the external thread **210** on the tower **209**. Alternatively an internal thread could be provided on the inside surface of the outer shield **230** engaging an external thread provided on the outside surface of the locking element **260**.

The locking element **260** is further provided with a number of protrusions **266** which extends in a proximal direction through openings **208** in the base portion of the hub **201** and into the hollow part **271** of the hub **201** housing the internal threads **202**. All though internal threads **202** are disclosed in the figures they could be replaced by a bayonet coupling without interfering with the way of operating the disclosed needle assembly.

A resilient element disclosed as a spring **250** is interfaced between the locking element **260** and the shield **240** urging the shield **240** in the distal direction and urging the locking element **260** in the proximal direction such that the locking element **260** in the initial position disclosed in FIG. **6**A abuts the hub **201**.

The locking element **260** is on its outside surface equipped with a number of axially extending ribs **262** and the shield **240** is on its inside surface provided with similar inwardly pointing ribs **242**. In the initial position the axially extending ribs **262** of the locking element **260** abuts the inwardly pointing rib **242** of the shield **240** thereby preventing the rib from telescoping relatively to the hub **201**.

When the hub **201** is attached to an injection device **220** having a cartridge **225** as disclosed in FIG. **6**B, the distal end of the injection device **220** will press the protrusions **266** on the locking element **260** through the holes **208** of the hub **201** and lift the locking element **260** out of abutment with the hub **201**. Due to the threaded connection **210**, **261** between the locking element **260** and the tower **209** of the hub **201**, the locking element **260** will be rotated during its axial movement. This rotation will cause the axially extending ribs **262** on the locking element **260** to be dislocated in relation to the inwardly pointing ribs **242** on the shield **240** thereby allowing the shield **240** to move in an axial direction relatively to the hub **201**.

It is evident that the axial extending ribs **262** and the inwardly pointing ribs **242** could be formed in many different ways, The function that the two elements **242**, **262** abuts each other in one position but are free of each other when rotated can be accomplished in many different ways e.g. by forming the ribs as protrusions or the like.

When the hub **201** is disconnected from the injection device, the spring **250** will urge the locking element **260** in the proximal direction which will cause the locking element **260** to be rotated back to the locked position. In this way the shield **240** is only allowed to telescope when the hub **201** is mounted on the injection device **220**.

Example 4

FIG. **7-8**

In the embodiment depictured in FIGS. **7** to **8**, the axial movement of the locking element **360** forces the arms **363** to move in a radial direction in and out of engagement with the safety shield **340**.

A spring **350** is mounted between the hub **301** and the safety shield **340**. In addition the spring **350** could apply pressure on the locking element **360** urging it in the proximal direction as explained below.

The locking element **360** has a number of arms **363** provided on a base **364** located in the connecting area **371** of the hub **301** having threads **302**, the arms **363** extends into the area distal to the hub **301** through openings **308** in the partition **307**. The geometry of the openings **308** in the partition **307** and the arms **363** is such that the arms **363** are forced to move in a radial direction when the locking element **360** is axially moved.

When the hub **301** carrying the needle cannula **315** is connected to the injection device the pressure applied on base **364** of the locking element **360** by the injection device **320** forces the locking element **360** to move in the distal direction which again forces the arms **363** to move in a radial direction towards the centre of the needle assembly thereby bringing the arms **363** out of engagement with the safety shield **340**. Once the arms **363** do no longer abut the safety shield **340**, the safety shield **340** can be moved telescopically in the proximal direction as disclosed in FIG. **8** B-C making it possible to perform an injection.

When the hub **301** is removed form the injection device, the geometry and elasticity of the arms **363** and partitions **307** forces the locking element **360** back into its initial position whereby the arms **363** are moved radial outward to a position beneath the safety shield **340** thereby preventing further movement of the safety shield **340**. The returning of the locking element **360** could also be assisted by not-shown arms on the base **364** penetrating through openings in the hub **301**, which not-shown arms would then be acted upon by the spring **350**.

Example 5

FIG. **9-10**

In the example disclosed in FIG. **9-10**, the hub **401** carrying the needle cannula **415** is provided with a number of distally extending arms **403**. In-between the arms **403** open slots **411** are provided. Further the hub **401** is provided with suitable connecting means **402** for connecting the needle assembly to an injection device.

On the external surface of the hub **401** a rotational outer shield **430** is provided. This shield **430** can rotate relatively to the hub **401**, which is further provided with a number of click-arms **412** which engages a toothed track **434** on the inside surface of the outer shield **430** such that this can only rotate in one direction relatively to the hub **401**.

The outer shield **430** is further provided with a number of guiding slits **433** guiding similar guiding ribs **443** on the outside of the safety shield **440**.

A spring **450** is located between the hub **401** and the safety shield **440** urging the safety shield **440** in the distal direction. Protrusions **441** on the safety shield **440** interact with a rim **431** on the outer shield **430** thereby preventing the safety shield **440** from be pressed out the opening **432** of the outer shield **430**.

The safety shield **440** is further provided with a number of inwardly pointing ribs **442** on its inside surface.

In the initial position disclosed in FIG. **10**A the ribs **442** on the inside surface of the safety shield **440** is positioned above the arms **403** provided on the hub **401**. This alignment prevents the safety shield **440** form axial movement.

When a user rotates the outer shield **430** relatively to the hub **401**, the safety shield **440** is forced to rotate due to the engagement between the guiding slits **433** on the outer shield **430** and the guiding ribs **443** on the outside of the safety shield **440**. This rotational movement rotates the inwardly pointing ribs **442** out of engagement with the arms **403** and into a position above the open slots **411** provided between the arms **403**. In this position the inwardly pointing ribs **442** of the safety shield **440** is free to move telescopically in the slots **411**. The click arms **412** and the toothed track **434** on the inside of the outer shield **430** control the rotational movement. When four arms **403** are present as disclosed in the FIGS. **9-10**, then the rotational movement between locked on unlocked position would be 45 degrees, however a different number of arms **403** and inwardly pointing ribs **442** can be used.

In order to lock the safety shield **440**, the user simply rotates the outer shield **430** and the safety shield **440** to its next position in which the inwardly pointing ribs **403** once again is positioned aligned with the arms **403**.

In this way a user can shift the needle assembly between its locked and its unlocked mode simply by rotating the outer shield **430** relatively to the hub **401** no matter if the needle assembly is mounted on an injection device **420** or not.

Example 6

FIG. **11-13**

An example very similar to the previous is disclosed in the FIGS. **11-13**. Here the rotational outer shield **530** engages the safety shield **540** by the guiding slits **533** engaging the guiding ribs **543** on the outside surface of the safety shield **540**.

The arms **563** obstructing the telescopically movement of the safety shield **540** is provided on a separate locking element **560** which in the initial position disclosed in FIG. **13**A prevents axial movement of the safety shield **540**. Longitudinal slots **569** are provided between the arms **563**.

The outer shield **530** is rotational mounted on the hub **501** carrying the needle cannula **510** by a groove **535** in the outer shielded **530** engaging a similar raised ring **513** on the hub **501**, and the rotational movement is controlled by the click arms **512** and the track **534** inside the outer shield **530**. The hub **501** is further provided with suitable connecting means **502** for connecting the needle assembly to an injection device **520**. However, when the needle assembly is not mounted on an injection device **520** the locking element **560** is urged by the spring **550** into a position where it abuts the hub **501**, and in this position depictured in FIG. **13**A the inwardly pointing ribs **542** of the safety shield **540** is positioned above the arms **563** such that the safety shield **540** is prevented from telescopically movement. The interaction between the click arms **512** and the track **534** is such that when the outer shield **530** is moved into its next guided position the inwardly pointing ribs **542** move to a position above the next arm **563**. So no matter in which guided position the outer shield **530** (and the safety shield **540**) is, no telescopically movement is allowed.

The locking element **560** is further provided with a number of fingers **566** which extend through openings **508** into the connecting area **571** such that the injection device **520** presses on the protrusion **566** when the needle assembly is mounted.

The locking element **560** is on its proximal side provided with cut-away parts **567** carrying a sloping edge **568**. This sloping edge **568** abuts a similar sloping protrusion **514** provided on the distal side of the hub **501**.

When a user mounts the needle assembly on an injection device **520** as depictured in FIGS. **13**B and **13**C, the injection devices **520** presses the locking element **560** in the distal direction. Due to engagement between the sloping edge **568** of the locking element **560** and the sloping protrusion **514** on the hub **501**, the locking element **560** rotates relatively to the hub **501** as it is moved distally.

This rotation moves the arms **563** and the slots **569** to a new position in which the arms **563** is located such relatively to the inwardly pointing ribs **542** on the safety shield **540** that the safety shield **540** can be shifted from a position in which the arms **563** are aligned with the inwardly pointing ribs **542** and a position where the inwardly pointing ribs **542** is aligned with the slots **569**. This means that once the needle assembly is mounted on the injection device **520** the user can rotate the outer shield **530** guided by the click arms **512** and the track **534** such that the safety shield **540** shifts between a locked and an unlocked position. As disclosed in the FIGS. **11** and **12** the slots **569** can be 90 degrees apart form each other in which case the outer shield **530** is moved 45 degrees in each rotation such that it shifts between locked and unlocked positions. However when the needle assembly is not mounted on an injection device **520** the inwardly pointing ribs **542** and the slots **569** are dislocated such that the inwardly pointing ribs **542** can never be in a position above a slot **569**. In this way it is secured that the position in which the safety shield **540** can telescope only can be obtained when the needle assembly is mounted on the injection device **520**. Once the needle assembly is dismounted the relative position between the arms **563** and the inwardly pointing ribs **542** are such that the safety shield **540** can never telescope, the inwardly pointing ribs **542** will be above an arm **563** no matter in which guided position the outer shield **530** (and the safety shield **540**) is in. It is understood that the location of the shiftable positions in the track **534** and the relative location of the inwardly pointing ribs **542** inside the safety shield **540** and the arms **563** and slots **569** are decisive for this.

Example 7

FIG. **14-15**

In the embodiment depictured in the FIGS. **14-15** no spring element as such is included. The hub **601** carries the needle cannula **615**, and a separate locking element **660** is provided between the hub **601** and the safety shield **640** which parts are encapsulated in the outer shield **630**.

The locking element **660** is further provided with fingers **666** which protrude through holes **608** in the hub **601**.

When the hub **601** is mounted on an injection device **620**, the distal end of the injection device **620** presses on the fingers **666** which makes the arms **663** of the locking element **660** deflect inwardly allowing the safety shield **640** to axially pass the locking element **660** as depictured in FIGS. **15**B and **15**C.

The safety shield **640** is internally provided with a plurality of conical flanges **644** which in use slides on the tower **609**. These conical flanges **644** replaces the spring member in the forgoing embodiments and works as the biasing means urging the safety shield **640** to the first position once the needle cannula **615** is retracted from the skin. In order to enhance the biasing force the tower **609** of the hub **601** slopes towards its distal end, further when the hub **601** is removed from the injection device **620** the flexibility of the base of the locking element **660** urges it back to its first position and the safety shield **640** is moved to its first position.

Example 8

FIG. **16-17**

In the embodiment depictured in the FIGS. **16** and **17**, the arms **763** on the locking element **760** deflect outwardly when the fingers **766** are activated by the injection device **720**. When the arms **763** are outwardly deflected as depictured in FIG. **17**B, the safety shield **740** is allowed to axially pass the locking element **760**.

Further the skirt of the safety shield **740** is divided into a plurality of skirt parts **745** which are pressed inwardly by the arms **763** of the locking element **760** when the safety shield **740** is moved to the position uncovering the needle cannula **715**. The arms **763** forms a conical sloping surface on the interior when deflected outwardly as depictured in the FIGS. **17**B and **17**C. The inwardly pressing of the skirt parts **745** on the conical sloping surface operates as a biasing mean urging the safety shield **740** back to its secured position when the needle cannula **715** is removed from injection site, further when the hub **701** is removed from the injection device **720** the flexibility of the base of the locking element **760** urges it back to its first position and the safety shield **740** is moved to its first position.

Example 9

FIG. **18-19**

FIGS. **18** and **19** discloses an embodiment in which the needle cannula **815** is attached to the hub **801**, further an outer shield **830** is attached to the hub **810**. Internally of the outer shield **830**, a safety shield **840** and a locking element **860** is provided with a spring **850** urging the two parts **840**, **860** from each other,

The locking element is provided with a finger **866** stretching through a hole **808** in the hub **801** and into the connecting area **871** of the hub **801**.

The locking element **860** is provided with a number of arms **863** which forms an angle with the axial axis X of the needle assembly as depictured in FIG. **19**A. In this non-activated position, the safety shield **840** is prevented from axial movement by the arms **863** of the locking element **860**. When an injection device **820** is attached to the connecting area **871**, the finger **866** of the locking element **860** is activated and the locking element **860** is forced into a position in which the

arms **863** is aligned with the axial axis X of the needle assembly as depictured in FIG. **19**B. In this position the safety shield **840** can move freely in the axial direction.

Example 10

FIG. **20-21**

This embodiment discloses a similar needle assembly however, the locking element **960** is only provided with one arm **963**. Further, the spring element **950** can be replaced by an elastic sponge **950**A as disclosed in FIG. **20**A. In fact in any of the embodiments disclosed any element providing a biasing force can be used instead of a spring.

Example 11

FIG. **22-23**

In this embodiment the locking element **1060** is provided with two arms **1063** which are deflected inwardly when the fingers **1066** are activated by the injection device attached to the needle assembly.

Example 12

FIG. **24**

In all the embodiments the element forming the outer barrier such as the outer shield **30** could be provided with an opening such as a window **36** through which a user can visually see the safety shield **40** or an element moving with the safety shield **40**. In this way the user can visually follow the progress of the injection. The element forming the background in the window **40** e.g. the locking member, could be coloured in a different colour than the element passing the window **36** e.g. the safety shield **40** during injection to enhance the visibility of the element passing the window **36**.

Example 13

FIG. **25-26**

In all the foregoing embodiments the needle assembly could be provided with a mechanism which provides the user with an audible, visual or tactile confirmation when the needle cannula is fully inserted.

An example of such audible mechanism is disclosed in FIG. **25**A-B. Here a mechanism **1180** carrying a click-arm **1181** is provided on the interior of the outer shield **1130**, the safety shield **1140** is at its proximal end provided with a peripheral rib **1141** which engages the click-arm **1181** once the safety shield **1140** is pressed fully back in order to provide a distinct sound informing the user that the needle cannula **1115** is fully inserted. This activation can be done in multiple ways e.g. as disclosed by having the click-arm **1181** carry a protrusion **1182** at the end, or the arm **1181** could carry more than one protrusion **1181**. The proximal end of the click-arm **1181** could e.g. be formed with a not-shown threaded portion providing a distinct sound as the rib **1141** slides over the threaded portion at the end of the needle insertion. In addition to providing a sound this would also provide a vibration of the needle assembly and the injection device to which it is attached thereby providing a tactile confirmation.

A further example of a visual and tactile indication is provided in the FIGS. **26**A-B. In this embodiment the click-arm **1181** is provided with an indicator **1183** e.g. a coloured indicator **1183** which is forced out of an opening **1136** in the outer shield **1130** once the shield reaches its proximal destination. This indicator **1183** could also be provided with a Braille-like indication.

Some preferred embodiments have been shown in the foregoing, but it should be stressed that the invention is not limited to these, but may be embodied in other ways within the subject matter defined in the following claims, e.g. could a needle assembly as herein described be delivered to the user in a rigid and sterile container which further could be shaped as a tool for assisting the user in mounting the needle assembly on to the injection device.

The invention claimed is:

1. A needle assembly for a drug delivery device comprising:

- a needle cannula mounted in a hub adapted to be connected to a drug delivery device via a connecting device of the needle assembly,
- a shield structured to telescopically move from a first position relative to the hub in which a tip of the needle cannula is substantially concealed by the shield, to a second position, in which at least the tip of the needle cannula is exposed,
- a biasing structure urging the shield towards the first position, and
- a releasable locking device structure co-operating with the connecting device of the needle assembly, wherein
  - the needle assembly is provided with the releasable locking device structure preventing telescopic movement of the shield and exposure of the tip of the needle cannula if the needle assembly is not mounted to a connecting device of a drug delivery device, and
  - the releasable locking device structure of the needle assembly allows telescopic movement of the shield and exposure of the tip of the needle cannula if the needle assembly is mounted to the connecting device of the drug delivery device.

2. A needle assembly according to claim **1**, wherein the releasable locking device structure is released when an object such as an injection device is connected to the connecting device of the needle assembly.

3. A needle assembly according to claim **1**, wherein the connecting device of the needle assembly is housed in the hub and the releasable locking device has one or more activating parts at least partly located in the area of the hub housing the connecting device of the needle assembly.

4. A needle assembly according to claim **3**, wherein the one or more activating parts are fingers protruding into the area of the hub housing the connecting device of the of the needle assembly.

5. A needle assembly according to claim **3**, wherein the one or more activating parts are activated when the connecting device of the needle assembly is utilized.

6. A needle assembly according to claim **1**, wherein the releasable locking device structure comprises a locking element locking the axial movement of the shield.

7. A needle assembly according to claim **6**, wherein the locking element carries locking arms engaging the shield.

8. A needle assembly according to claim **6**, wherein the locking element is rotatable relative to the hub.

9. A drug delivery device and needle assembly system comprising:

- a drug delivery device and a needle assembly, each having a connecting device such that the drug delivery device and the needle assembly are structured to connect to each other via the connecting device of the drug delivery device and the connecting device of the needle assembly,
- wherein
- the needle assembly comprises:
  - a needle cannula mounted in a hub having the connecting device for connecting the hub to the drug delivery device,
  - a biased shield movable relative to the hub from a first position in which a tip of the needle cannula is substantially concealed by the shield to a second position in which at least the tip of the needle cannula is exposed, and
  - a releasable locking device structure co-operating with the connecting device of the needle assembly to lock the shield in the first position, wherein the locking device structure is provided with structure to:
    - unlock if the needle assembly is mounted to the connecting device of the drug delivery device allowing movement of the shield relative to the hub, and
    - lock if the needle assembly is not mounted to the connecting device of the drug delivery device preventing movement of the shield relative to the hub.

10. A drug delivery device and needle assembly system according to claim **9**, wherein the shield can be shifted between a locked and an unlocked position only when the needle assembly is connected to the injection device.

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